



Wockhardt Limited

Consolidated ESG Statement

FY 2025-26

Wockhardt Limited

Consolidated ESG Statement

Table of Contents

1. Executive Summary

2. Description of Organisation

3.1 Description of Processes

4. Environmental Profile

4.1 Certifications and Endorsements

5. Environmental Policy

5.1 Policy Objectives

6. Outline of Management System

6.1 System Governance and Oversight

List of Policies – Wockhardt Limited

6.2 Key Outcomes

7. Communication and Consultation

7.1 Stakeholder Consultation Framework

7.2 Key Highlights

8. Environmental Aspects

Table 1: Energy Consumption Data

8.1 Assessment and Prioritization

8.2 Mitigation and Controls

Emissions

Table 2: Emission Data

Table 3: Biotech Briquettes Boilers Emission Data From Jan 2013 To Mar 2026

Table 4: Shendra Briquettes Boilers Emission Data From Nov 2016 To Mar 2026.

Key Performance Indicators

Table 5: Key Performance Indicators

Water Consumption

Table 6: Water Consumption Data

Table 7 : Water Management Metrics and Objectives

Waste Management

Table 8 : Waste Management Metrics

Training & Awareness Programmes

Table 9 : Training and Awareness Metrics

Gender Pay Indicators

Table 10 : Gender Pay Indicators

Hiring & Performance Appraisal

Table 11 : Hiring

Table 12 : Hiring – Data Breakdown (FY 2024)

The Wockhardt Group ESG Objectives

The Future

Wockhardt Limited

Carbon Reduction Plan

Wockhardt Carbon Reduction Road Map

Wockhardt Net Zero Roadmap

Introduction

Scope 1

Scope 2

Scope 3

Table 1: The Global Warming Potential of the Greenhouse Gases

Boundary of Assessment

Table 2: Boundaries for the Pharmaceutical Industry for Scope 3

Wockhardt Limited Carbon Reduction Plan – March 2025

Table 3: NHS Scope 3 Categories

Wockhardt Limited Carbon Reduction Plan – March 2025

Scope 1 and 2 Assessment

Short term Goals

Short-term improvement goal to achieve a reduction of 10% for 2025/6 for Scope 1 and 2 combined

Long term Goals

Conclusion

APPENDIX OVERVIEW

APPENDIX 1: Assurance Certificate And UK Carbon Reduction Report

APPENDIX 2: Energy Conservation & Technology Absorption At Wockhardt Ltd FY 2025 -2026

APPENDIX 3: Renewable Energy Certificates

(Renewable Energy Certificate)

APPENDIX 4: ISO Certificates

(ISO Certificates)

APPENDIX 5: Rain Water Harvesting Certificate

APPENDIX 6: Waste Management Certificates

Packaging Waste Recovery

E-Waste Certificate

APPENDIX 7: Quality Assurance Certificates (GMP)

(Biotech API Certificates)

(Daman Bhimpore)

(Daman Kadaiya)

(Ankleshwar)

(Shendra)

GMP Certificates

(Pinewood Certificates)

1. Executive Summary

Wockhardt Limited provides a sustainability performance overview covering environmental management, operations, and corporate responsibility initiatives. The organization has set targets for **emissions reduction**, aiming for a **50% decrease** in absolute emissions by 2030 (taking 2021 as the base year) and **net-zero emissions** by 2050, supported by the implementation of renewable electricity across operations. The environmental management systems align with **ISO 14001 standards**, with energy sub-metering infrastructure enabling resource consumption monitoring and optimization. The waste management protocols encompass e-waste and hazardous materials handling, incorporating recycling processes. Safety metrics indicate **one critical incidents** across operations. The governance structure incorporates ESG (Environment, Social, and Governance) and Corporate Social Responsibility (CSR) Committees, which oversee the implementation of sustainability initiatives. These measures reflect Wockhardt Limited's approach to integrating business operations with environmental and social responsibility standards.

2. Description Of Organisation

Wockhardt Group globally operates Biotech and Pharma manufacturing, research and development centres in India, UK and Ireland. The consolidated ESG (Environment Social Governance) report includes the consolidated data and the actions being taken collectively in Wockhardt Group entities in India, UK, Ireland.

3.1 Description Of Processes

The Wockhardt Group operates through established processes to maintain operations across its global facilities. Wockhardt Limited's manufacturing capabilities include production of **sterile pharmaceutical products**, with facilities equipped for manufacturing cartridges, ampoules, and vials using both aseptic preparation and terminal sterilization methods. The Environmental, Health, and Safety (EHS) system integrates **energy-efficient equipment**, waste stream management protocols, and emissions control measures to address environmental impacts across air, land, and water mediums. The sustainability framework aligns with **Paris Agreement parameters**, incorporating decarbonization targets and establishing a specific goal to reduce organizational waste to less than **1% of material consumption** by 2030. The operational infrastructure incorporates **digital transformation** through automation and AI implementation, advanced logistics and inventory management systems, alongside vendor engagement protocols that integrate sustainability criteria. The quality assurance framework includes internal audits, employee training programs, and management reviews to maintain compliance with international standards and facilitate continuous improvement. These operational and sustainability processes constitute the foundation of Wockhardt Limited's pharmaceutical manufacturing operations, supporting their continued participation in the pharmaceutical sector.

4. Environmental Profile

Wockhardt Limited's environmental management system aligns with **ISO 14001 standards** and includes externally audited registers to track direct and indirect environmental impacts. The organization has established environmental targets, which include transitioning to **100% renewable electricity** usage and reducing emissions by **50% by 2030**, with the long-term objective of achieving **net zero emissions** by 2050. The environmental framework incorporates quantifiable objectives, including a targeted **5% annual reduction** in energy intensity per unit of turnover, an annual increase in green cover by 5% to align with global environmental standards, and maintaining waste generation below 1% of material consumption. The waste management protocols ensure complete recycling of e-waste and battery waste through authorized government channels. The environmental management framework incorporates regular audits, inspections, and improvement processes to maintain environmental standards and sustainable operational practices within the pharmaceutical sector. Wockhardt holds a valid E-Waste Management Certificate and is registered under the Extended Producer Responsibility (EPR) framework with the Central Pollution Control Board (CPCB), ensuring responsible disposal and management of electronic waste. *(Refer Annexure for details)*

4.1 Certifications And Endorsements

Across its entities, the Group holds certifications and adheres to international environmental standards, including:

- ISO 14001 certification.
- Compliance with local and international waste management regulations.
- Wockhardt has achieved an EcoVadis Bronze rating, reflecting our ongoing commitment to improving sustainability performance across environmental, social, and ethical criteria.
- Wockhardt ensures compliance with the Central Pollution Control Board (CPCB), adheres to Extended Producer Responsibility (EPR) mandates, and conforms to both local and international waste management regulations.

5. Environmental Policy

Wockhardt Limited's Environmental Policy outlines the organization's approach to **environmental protection**, impact reduction, and sustainable development. The policy framework incorporates environmental criteria into business decisions, adhering to global standards through **ISO 14001 certification** and alignment with the **Paris Agreement's 1.5°C** global warming limitation target. The environmental objectives include achieving **net zero emissions by 2050**, with an intermediate target of **50% absolute emissions reduction by 2030**. The policy encompasses multiple environmental management areas, including programs for energy intensity reduction, renewable energy adoption, and waste management protocols that maintain full compliance with recycling regulations for hazardous materials and electronic waste. The environmental framework extends to supply chain operations through integrated sustainability criteria. The policy undergoes systematic reviews and updates to maintain alignment with environmental requirements and organizational objectives within pharmaceutical manufacturing operations.

5.1 Policy Objectives

- **Energy Efficiency:** Continuously optimise energy usage to reduce carbon intensity.
- **Waste Management:** Promote the reduction, reuse, and recycling of materials across operations.
- **Compliance and Standards:** Adhere to local and international environmental laws and standards.
- **Stakeholder Engagement:** Foster collaboration with employees, suppliers, and local communities to promote environmental awareness and action.

6. Outline Of Management System

Wockhardt Limited operates an **Environmental, Health, and Safety (EHS) Management System** to support operational and sustainability objectives. The system utilizes a **multi-tiered framework** that incorporates digital monitoring capabilities, management protocols, and compliance mechanisms across global facilities. The operational structure includes **monthly senior management reviews**, performance evaluations, and employee training programs to maintain alignment with international EHS standards. The organization implements sustainability practices throughout the **value chain**, utilizing digital systems for EHS performance monitoring and analysis. The framework incorporates **vendor engagement** to align supply chain operations with environmental objectives, supported by regular audits and compliance verification processes. The operational infrastructure integrates **decarbonization initiatives** within core processes to address environmental management requirements.

6.1 System Governance And Oversight

- Wockhardt's system of governance and oversight involves the ESG (Environment Social Governance) Committee, CSR (Corporate Social Responsibility) Committee, Risk Management Committee, and senior leadership teams, for responsibility and accountability.
- Regular internal audits, external certifications, and stakeholder feedback mechanisms are in place to maintain transparency and drive improvement.

List Of Policies – Wockhardt Limited

Policy Name	
Acceptable Usage Policy for IT Systems	Patent Policy
Anti-bribery and Anti-corruption policy	Policy for Preservation of Documents
Anti-Trust and Fair Competition Policy	Policy for determining materiality of events
Archival Policy	Policy for determining Material Subsidiaries
Board Diversity Policy	Policy on Related Party Transactions
Business Responsibility and Sustainability Policy	Risk Management Policy
Code of Business Conduct and Ethics	Remuneration Policy
Code of Conduct for Regulating, Monitoring and Reporting of Trading by Designated Persons	Stakeholders grievance Policy
Code for fair disclosure of Unpublished Price Sensitive Information	Template for Appointment of Independent Directors
Communications Policy	Whistle Blower Policy
Corporate Social Responsibility Policy	Wockhardt Cybersecurity Policy
Data Privacy Policy	Wockhardt Quality Policy
Diversity, Inclusion and Equal Opportunity Policy	
Dividend Distribution Policy	
Environment, Health, Safety & Sustainability Policy	
Forex Risk Management Policy	
Human Rights Policy	
Policy for Familiarisation Programmes for Independent Directors	

Link: <https://www.ockhardt.com/investors/corporate-governance/policies-codes/>

6.2 Key Outcomes

- Enhanced operational efficiency through streamlined EHS processes.
- Continuous improvement in energy usage, waste management, and emissions reductions.
- Stronger alignment with global environmental standards and stakeholder expectations.

The Wockhardt Group's management systems form the backbone of its sustainability strategy, enabling the entities to deliver on their environmental commitments while fostering a culture of accountability and innovation.

7. Communication And Consultation

Wockhardt Limited maintains a **stakeholder engagement framework** that facilitates communication regarding environmental, social, and governance initiatives. The engagement infrastructure incorporates **employee training programs**, monthly review meetings, and feedback mechanisms through departmental channels. The organization provides transparency through **annual sustainability reporting** and maintains community engagement through sponsorships and partnerships. Internal communications utilize **corporate newsletters** and an intranet platform to distribute organizational information. The stakeholder engagement processes include periodic consultations with community members and vendors to align with sustainability objectives. The framework incorporates **grievance mechanisms** to address environmental and social impact concerns. The organization conducts environmental awareness programs and provides updates on legal and environmental requirements during employee orientation to support organizational knowledge and sustainability alignment.

7.1 Stakeholder Consultation Framework

- **Employees:** Feedback sessions and training programs to build awareness and capability.
- **Community:** Collaborative initiatives to foster long-term partnerships and mutual benefits.
- **Vendors:** Regular dialogue is maintained to ensure their operations align with Wockhardt's environmental, social, and governance standards.

7.2 Key Highlights

- Transparent communication of key environmental metrics, including energy use, waste management, and emissions reductions.
- Inclusion of stakeholder inputs in policy and program development to ensure relevance and effectiveness.
- Active dissemination of ESG achievements and goals through sustainability reports and public disclosures.

8. Environmental Aspects

Wockhardt Limited operates an **Environmental, Health, and Safety (EHS) system** to identify and manage environmental factors across global operations. The environmental aspect register undergoes **annual updates** to prioritize sustainability initiatives and track environmental performance metrics. The environmental targets include a **5% annual reduction** in energy intensity for Scope 1 and Scope 2 emissions management, contributing to the organizational target of **50% emissions reduction by 2030**. The waste management protocols maintain **waste generation below 1%** of material consumption, with established recycling systems and full compliance with hazardous waste recycling requirements through authorized government channels. The environmental monitoring framework includes **air and water quality verification**, with specific protocols for NOx and SOx emissions to meet regulatory standards. The operational infrastructure incorporates renewable electricity adoption and **water conservation measures** across facilities to address environmental impact requirements.

Table 1: Energy Consumption Data

Data Metrics	Sub metric	Units
Energy Data	Total Energy Consumed from Renewable Sources (in GJ)	194,961.24
	Total Energy Consumed (in GJ)	600,451.32
	Renewable Energy Consumption %	32.47%
	Total Emissions Saved (tCO ₂ e)	37,040.76

8.1 Assessment And Prioritization

Environmental aspects are evaluated based on factors such as:

- **Legislation:** Compliance with local, national, and international environmental laws.
- **Stakeholder Concerns:** Addressing key issues raised by employees, communities, and regulators.
- **Severity and Frequency:** Assessing the potential environmental impact and likelihood of occurrence.

8.2 Mitigation And Controls

1. Regular audits and inspections to ensure adherence to environmental standards.
2. Development and implementation of targeted objectives, such as energy sub-metering and waste reduction programs.
3. Focused efforts to reduce significant impacts through innovative solutions and employee engagement

Emissions

Wockhardt Limited monitors and manages its greenhouse gas (GHG) emissions across operations through structured data tracking and targeted reduction initiatives. During the reporting period, total GHG emissions were 106,896.23 tCO₂e, comprising Scope 1 emissions of 13,022.86 tCO₂e, Scope 2 emissions of 49,679.83 tCO₂e, and Scope 3 emissions of 44,193.54 tCO₂e. The Company reports a Scope 1 and Scope 2 emissions intensity of 0.037 tCO₂e per million INR of revenue, while Scope 3 emissions intensity stands at 0.026 tCO₂e per million INR.

The organization's climate action framework aligns with science-based targets, with commitments toward achieving net-zero emissions by 2050 and a 50% reduction in emissions by 2030. Scope 2 emissions are being addressed through increased adoption of renewable electricity, including full transition at select facilities. Scope 1 emissions are managed through fuel efficiency improvements and adoption of cleaner fuels, supported by investments in renewable energy infrastructure. The emissions management approach is reinforced by robust monitoring systems and reporting mechanisms aligned with international standards for climate and environmental management.

Table 2: Emission Data

Data Metrics	Sub metric	Values	Unit
Emission Data	Scope 1	13,022.86	tCO ₂ e
	Scope 2	49,679.83	tCO ₂ e
	Scope 3	44,193.54	tCO ₂ e
	Total Scope 1 and Scope 2 emission intensity per rupee of turnover (Total Scope 1 and Scope 2 GHG emissions / Revenue from operations)	0.037	tCO ₂ e/Mn.Rs
	Total Scope 3 emissions per rupee of turnover	0.026	tCO ₂ e/Mn.Rs

Table 3: Biotech Briquettes Boilers Emission Data From Jan 2013 To Mar 2026

Jan 2013 To Mar 2025		
Savings at Biotech Park from Briquettes Boilers		
Data Metrics	Values	Unit
Carbon Emissions from Briquettes	4,571.47	tCO ₂ e
Carbon Emissions from FO	73,103.90	tCO ₂ e
Carbon Emissions Saved	68532.43	tCO ₂ e

Table 4: Shendra Briquettes Boilers Emission Data From Nov 2016 To Mar 2026.

Nov 2016 To Mar 2025		
Savings at Shendra from Briquettes Boilers		
Data Metrics	Values	Unit
Carbon Emissions from Briquettes	848.37	tCO ₂ e
Carbon Emissions from FO	12,414.12	tCO ₂ e
Carbon Emissions Saved	11565.72	tCO ₂ e

Key Performance Indicators

Table 5: Key Performance Indicators

Category	Metric	Wockhardt Group Level Value
Environmental Performance	Total Energy Consumption (in GJ)	600,451.32
	Renewable Energy Consumption (in GJ)	194,961.24
	Renewable Energy Consumption %	32.47%
	Avoided Emissions (in tCO ₂ e)	37,040.76*
	Total Water Withdrawal (in kL)	911,887.05
	Total Waste Processed (in metric tonne)	2,674.93
	Waste Recycling Rate (%)	59.17
	Total Scope 1 and Scope 2 Emissions (tCO ₂ e)	62,702.69
	Scope 1 Emissions (tCO ₂ e)	13,022.86
	Scope 2 Emissions (tCO ₂ e)	49,679.83
	Total Water Withdrawal (in kilo liters)	911,887.05
	Water discharge by destination and level of treatment (in kilolitres)	361,571 kL Treated effluent sent to common effluent treatment plant (CETP)
	Rainwater Harvested	37.85 million litres
Social Metrics	Female Employee Representation (%)	14.98%
	ESG and Compliance Training Programs (count of programs annually)	533.00
	Employees Trained in ESG (%)	68.68%
	Critical Health and Safety Incidents	0
Governance Metrics	Regulatory Compliance	Full compliance with environmental and regulatory requirements.

Category	Metric	Wockhardt Group Level Value
		ISO 14001, ISO 45001, ISO 13485:2016, GMP Certifications
	Governance Framework	Anti-bribery and corruption policies, stakeholder engagement, and community consultation mechanisms
Quality Assurance	Quality Assurance Certifications	ISO 9001, ISO 14001, cGMP Certifications

* EF consideration

Ireland: $\approx 0.0670 \text{ tCO}_2\text{e/GJ}$

India: $\approx 0.1972 \text{ tCO}_2\text{e/GJ}$

UK: $\approx 0.0486 \text{ tCO}_2\text{e/GJ}$

Water Consumption

Wockhardt Limited implements structured water management protocols across its manufacturing operations. During the reporting period, the total water withdrawal was 911,887.05 KL, primarily sourced from surface water (457,502.00 KL; ~50.2%) and third-party water (290,941.53 KL; ~31.9%), followed by other sources (143,594.05 KL; ~15.7%) and groundwater (19,849.45 KL; ~2.2%), with no dependence on seawater/desalinated water. The Company's total water consumption stood at 493,352.54 KL. Its water management approach integrates closed-loop systems, process optimization, and reuse of treated wastewater for landscaping and other non-potable applications. The framework is supported by periodic water audits, source monitoring, and compliant wastewater treatment infrastructure, with 361,571 KL of treated effluent discharged to CETP. Additionally, rainwater harvesting contributed 37.85 million litres, reinforcing the Company's commitment to sustainable water stewardship. Water intensity is maintained at 0.29 KL per million INR of revenue, reflecting efficient resource utilization.

Table 6: Water Consumption Data

Data Metrics	Sub metric	Figures
Water Consumption Data	(i) Surface water (in kilolitres)	457,502.00
	(ii) Ground water (in kilolitres)	19,849.45
	(iii) Third Party Water (in kilolitres)	290,941.53
	(iv) Seawater / desalinated water (in kilolitres)	0
	(v) Others (in kilolitres)	143,594.05
	Total volume of water withdrawal (in kilolitres) (i + ii + iii + iv + v)	911,887.05
	Total volume of water consumption (in kilolitres)	493,352.54
	Rainwater Harvested (in million litres)	37.85
	Water intensity per rupee of turnover (Total water consumption / Revenue from operations) (In kL/Mn Rs)	0.29
	Water discharge by destination and level of treatment (in kilolitres)	361,571 kL Treated effluent sent to common effluent treatment plant (CETP)

Table 7 : Water Management Metrics And Objectives

Category	Metric	Value/Description
	Purpose of Recycled Water	Landscaping and non-potable applications
Infrastructure and Processes	Water Management Infrastructure	Closed-loop systems, process optimization measures
	Wastewater Treatment	Facilities meeting regulatory requirements
Operational Framework	Water Audits	Conducted to ensure sustainable usage patterns

Category	Metric	Value/Description
	Withdrawal Source Monitoring	Implemented
Environmental Metrics	Water Intensity Metrics	Tracked
	Community Engagement	Ensures water resource access and ecosystem impact management
Environmental Objectives	Overall Goal	Supports environmental management objectives and community considerations

Waste Management

Our E-waste management protocol adheres to comprehensive environmental standards and regulatory compliance. All electronic waste is securely collected and stored for a two-year period before undergoing processing. The disposal process strictly follows local, state, and central government regulations, ensuring environmentally sustainable recycling and destruction methods. Documentation of compliance is maintained through E-waste certificates. (ref Appendix 5).

Table 8 : Waste Management Metrics

Category	Metric	Value/Description
Waste Management Performance	Total Waste Processed (in metric tonne)	2,674.93
	Recycling Rate	59.17 %
	Types of Recycled Waste	Glass, electronic waste, and batteries
	Waste Reduction Target	Reduce waste generation to less than 1% of material consumption by 2030
Operational Framework	Source Segregation Protocols	Implemented
	Partnerships	Collaboration with government-certified vendors
	Compliance	Full compliance with hazardous waste management regulations
	Employee Training	Training on waste handling procedures and reduction methodologies
Environmental Impact	Process Optimization	Measures in place to minimize waste generation
	Landfill Utilization	Reduced through recycling and waste management processes
	Regulatory Alignment	Maintained

Training & Awareness Programmes

Wockhardt Ltd undertakes structured training and awareness programmes for employees, management, and leadership to strengthen organizational capabilities, enhance compliance awareness, and build future-ready skills. These programmes span key areas such as POSH and business ethics, ESG, cybersecurity, data protection, leadership development, digital tools, and functional competencies. During the reporting period, the Company conducted **50 training programmes**, covering a total of **14,926 participants (13,307 male and 1,514 female employees)**, with an aggregate of **10,674.5 training hours**. Key initiatives included POSH compliance and business ethics (935 participants), ESG training (893 participants), DPDPA and cybersecurity programmes (727 participants each), and large-scale engagement through LOGIQ quizzes (11,099 participants).

This extensive coverage reflects Wockhardt Ltd's strong commitment to continuous learning, regulatory compliance, and employee capability building, ensuring a well-informed and future-ready workforce.

Table 9 : Training And Awareness Metrics

No. of Program	Programs	Male	Female	Participant Count	Total Hours
7	POSH Compliance and Business Ethics	719	144	935	935
4	ESG Training	723	170	893	893
1	DPDPA	603	124	727	363.5
1	Cyber Security	603	124	727	363.5
4	Leveraging AI for Smart Work & Communication	124	37	161	322
2	Ethics, Professional Conduct & Corporate Responsibility	50	4	54	108
1	Goal Setting	17	3	20	40
1	Train the trainer	27	4	31	496
1	Leadership Qualities & Team Management	5	6	11	88
1	Excel Dashboard	5	1	6	12
6	Sales Training Program	155	8	196	1372
18	LOGO quiz	10212	887	11099	5549.5
3	Refresher / Booster	64	2	66	132
50	Total	13307	1514	14926	10674.5

Gender Pay Indicators

The Company conducts and discloses its gender pay analysis, which highlights pay differences across employee categories. While women show comparatively higher earnings than men on mean and median measures at an overall level, significant variations exist at specific levels — particularly at the executive level, where male base salaries are substantially higher than those of women. The absence of cash incentives at management levels indicates that pay structures are primarily fixed in nature, reflecting both gaps and balances within the compensation framework.

Table 10 : Gender Pay Indicators

Category	Metric	Value/Description
Executive Level Pay	Base Salary – Women	1,284,000 INR
	Base Salary – Men	30,067,000 INR
Management Level Pay	Base Salary – Women	2567732 INR
	Base Salary – Men	2711246 INR
Non-Management Level Pay	Base Salary – Women	742500 INR
	Base Salary – Men	626963 INR
Gender Pay Gap	Mean Difference	Female (20.12%) higher than Male
	Median Difference	Female (23.70%) higher than Male
	Mean bonus gap	7.31%
	Median bonus gap	9.33%

Hiring & Performance Appraisal

The Company continues to disclose transparent information on its hiring practices and employee evaluation framework. Hiring trends indicate a calibrated approach with fewer new hires in FY 2024 compared to FY 2023, reflecting focused recruitment and optimized internal mobility. The Company maintains cost-efficient recruitment practices with detailed disclosure of hires by age, gender, and management levels. Performance appraisals are conducted annually, and the appraisal outcomes are finalized by the respective Function Head, ensuring consistency, accountability, and fairness in employee assessments while aligning performance with organizational objectives.

Table 11 : Hiring

Metric	FY 2021 - 22	FY 2022 - 23	FY 2023 - 24	FY 2024 - 25	FY 2025 - 26
Total number of new employee hires	838	675	680	503	884
Percentage of open positions filled by internal candidates (internal hires)	12.3%	12.4%	7.6%	2%	15.2%
Average hiring cost/FTE Currency: INR	0.074	0.069	0.068	0.086	0.071

Table 12 : Hiring – Data Breakdown (FY 2024)

Category	Sub-category	Number of Hires
Age Group	<25 years	173
	26–30 years	363
	31–35 years	182
	36–40 years	84
	41–45 years	49
	>45 years	33
Gender	Male	807
	Female	77
Management Level	Junior	829
	Middle	47
	Senior/Top	8

The Wockhardt Group ESG Objectives

The Wockhardt Group established a series of ambitious objectives, focusing on enhancing environmental sustainability, fostering social responsibility, and reinforcing governance practices. These objectives are aligned with the Group's long-term sustainability vision and international standards.

Environmental Objectives:

1. **Energy Management:**
 - Transition an additional 10% of energy consumption to renewable sources across all entities.
 - Reduce energy intensity per unit of output by 5% compared to 2022 levels.
 - Install solar panels at two additional manufacturing facilities.
2. **Water Management:**
 - Increase water recycling rates by 10% to further reduce dependency on freshwater sources.
 - Implement advanced water monitoring systems across all major sites.
 - Reduce water withdrawal intensity by 8% from baseline levels.
3. **Waste Management:**
 - Reduce hazardous waste generation by 10%.
 - Achieve a 90% recycling rate across all waste streams.
 - Eliminate non-compliant disposal practices through vendor and employee training.
4. **Emissions Reduction:**
 - Reduce Scope 1 and Scope 2 GHG emissions by 5% each year as part of the Group's science-based targets.
 - Expand the use of electric vehicles for internal logistics at three facilities.

Social Objectives:

1. **Employee Welfare:**
 - Conduct health and safety training for 100% of the workforce.
 - Increase female representation in the workforce by 3%, focusing on leadership roles.
2. **Community Engagement:**
 - Launch two new CSR initiatives focused on healthcare and education in local communities.
 - Collaborate with local governments to support clean water and sanitation projects.

Governance Objectives:

1. **Compliance and Transparency:**
 - Achieve external assurance for sustainability reporting across all entities.
 - Conduct quarterly ESG reviews to monitor and address material issues proactively.
2. **Stakeholder Engagement:**
 - Expand vendor engagement programs to ensure alignment with sustainability goals.
 - Host two stakeholder consultations to gather feedback on the Group's sustainability initiatives.

Key Milestones:

- Strengthening ESG integration across all business operations.
- Enhancing tracking mechanisms to measure progress against defined targets.
- Aligning short-term objectives with long-term goals of achieving net zero by 2050.

The Future

The Wockhardt Group remains steadfast in its commitment to driving sustainability across all aspects of its operations. Looking ahead, the Group has outlined a visionary roadmap to address emerging challenges, leverage opportunities, and achieve long-term sustainability goals.

Environmental Goals:

1. **Net Zero Commitment:**
 - Achieve net zero emissions by 2050, with interim targets including a 50% reduction in Scope 1 and 2 emissions by 2030.
 - Expand renewable energy usage to 75% of total energy consumption by 2035.
2. **Water Stewardship:**
 - Attain 50% water recycling across all sites by 2030.
 - Implement advanced water efficiency technologies to reduce water withdrawal intensity by 20% from baseline levels.
3. **Circular Economy:**
 - Enhance waste management practices to achieve zero waste to landfill by 2040.
 - Develop innovative recycling solutions for hazardous and non-hazardous waste streams.

Social Vision:

1. **Employee Development:**
 - Increase female participation in leadership roles to 25% by 2030.
 - Conduct comprehensive health and safety training for 100% of the workforce annually.
2. **Community Engagement:**
 - Double the investment in CSR initiatives, focusing on education, healthcare, and environmental conservation.
 - Partner with local governments and NGOs to scale impactful community programs.

Governance Enhancements:

1. **Data Transparency:**
 - Integrate advanced digital tools to improve ESG data collection, analysis, and reporting.
 - Achieve external assurance for all sustainability disclosures by 2025.
2. **Stakeholder Collaboration:**
 - Host annual multi-stakeholder forums to gather diverse perspectives and feedback on sustainability efforts.
 - Strengthen vendor and supply chain partnerships to align with evolving ESG expectations.

Key Strategic Focus Areas:

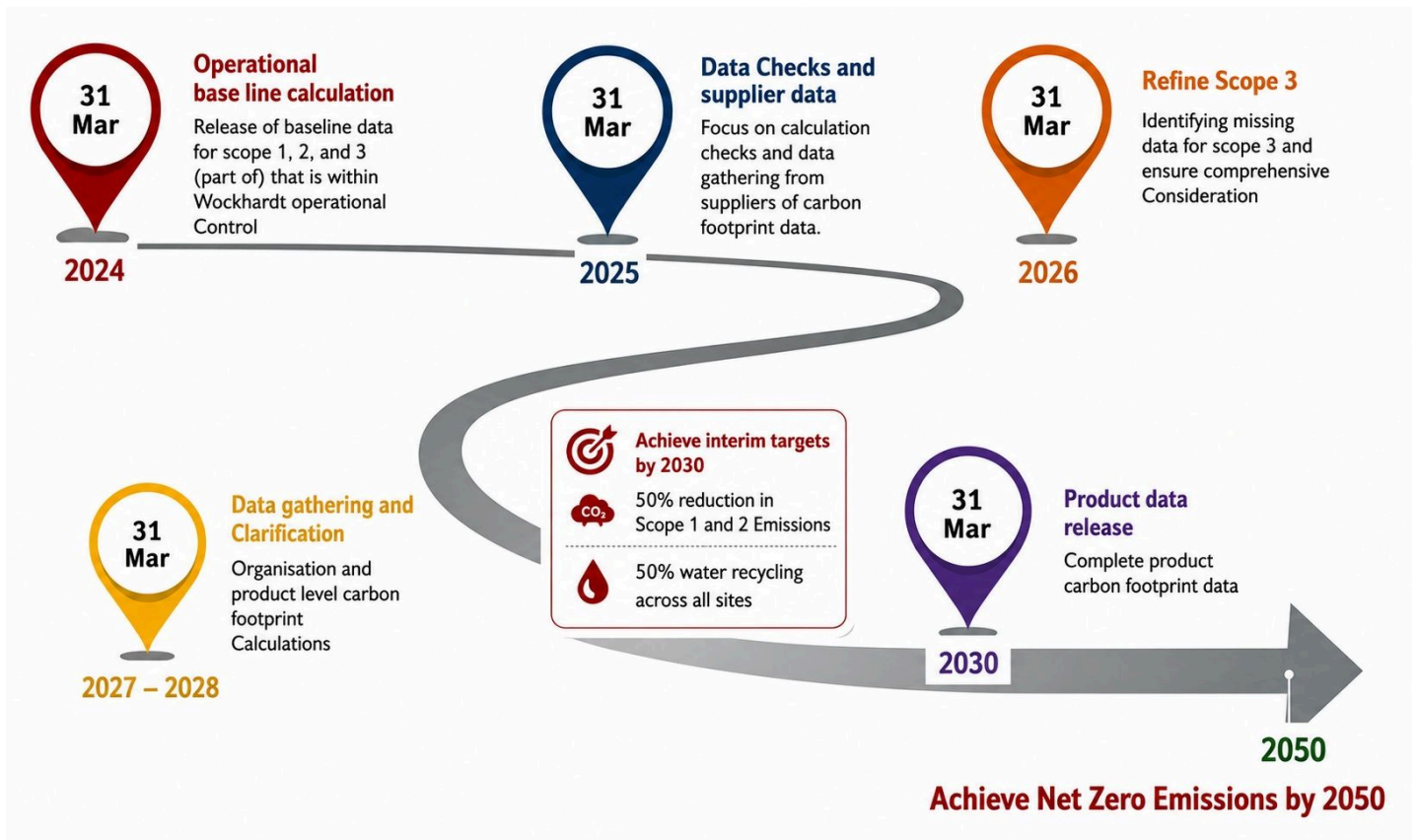
- Embracing innovation to accelerate sustainability initiatives.
- Strengthening stakeholder relationships to foster collective progress.
- Continuously adapting to regulatory and market dynamics to remain a leader in sustainable practices.

Wockhardt Limited

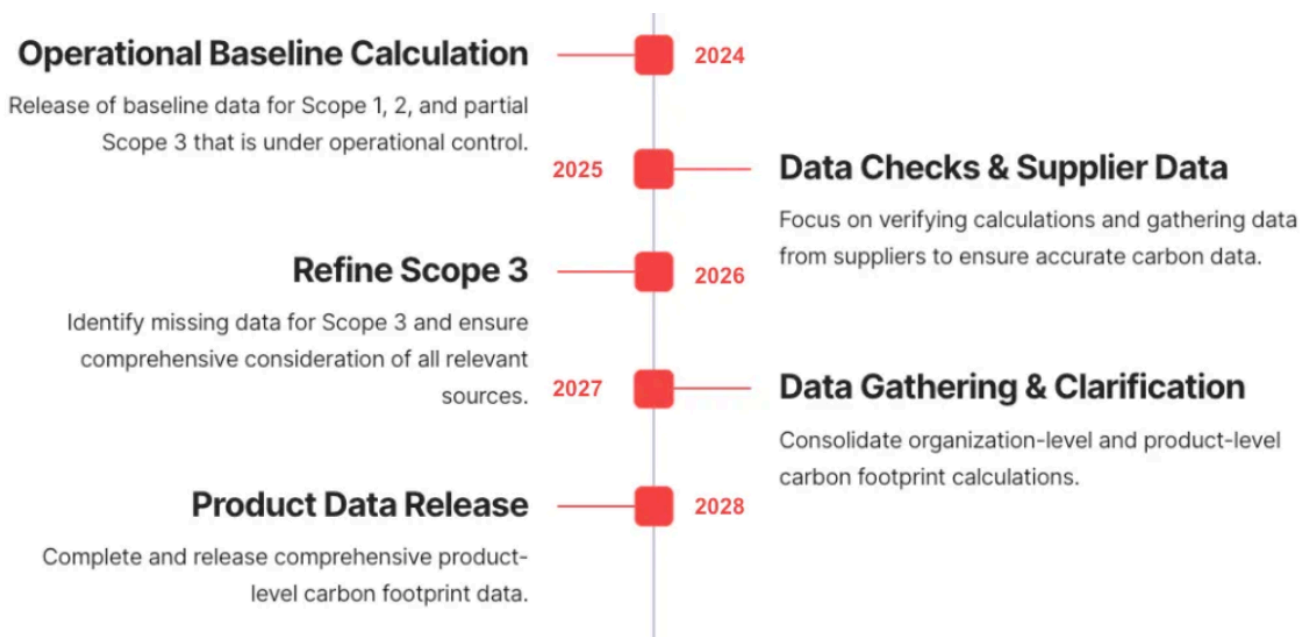
Carbon Reduction Plan



Wockhardt Carbon Reduction Road Map



Wockhardt Net Zero Roadmap



Introduction

Carbon footprints are used to present carbon emissions associated with an organization. This provides a basis for monitoring emissions in the future and for tracking progress towards carbon reduction targets and identifying hotspots to focus mitigation initiatives.

A carbon footprint refers to the total greenhouse gas emissions (GHGs) caused directly and indirectly by an individual, organization, event, or product. The Global Warming Potential (GWP) of each greenhouse gas may be expressed in CO₂ equivalents, see Table 1. As noted within the table, those gases with a high global warming potential can mean a small emission has a considerable impact. The GWP of a gas is its relative potential contribution to climate change over a 100-year period (where CO₂ = 1).

Carbon footprints are typically focused on direct and indirect emissions. Direct emissions arise from those sources that are owned or controlled by the organization. These are differentiated from indirect emissions that still result due to the organization's activities; however, the releases occur at sources owned or controlled by other entities. By convention, assessment is based on the Greenhouse Gas (GHG) Protocol (<https://ghgprotocol.org/>) that focuses on scope 1, 2, and 3 emissions as appropriate.

Scope 1

Stationary Combustion: Direct GHG emissions from stationary combustion. Stationary fuel combustion emission sources are typically devices that combust solid, liquid, or gaseous fuel.

Fugitive Emissions: From refrigeration and air conditioning result from leakage and service over the operational life of the equipment and from disposal at the end of the useful life of the equipment. The leakage of refrigerant gas is a small but significant source of GHG emissions because of a high GWP associated with these GHGs.

Mobile Combustion Emissions: From owned or leased mobile sources (both on-road and non-road vehicles) that are within the company's inventory boundaries.

Scope 2

Emissions from Purchased Energy

Scope 3

All Other Indirect Emissions from activities of the organization, occurring from sources that they do not own or control. These are usually the greatest share of the carbon footprint, covering emissions associated with business travel, procurement, waste, and water.

Table 1: The Global Warming Potential Of The Greenhouse Gases

Kyoto Gas / Greenhouse Gas	GWP
Carbon Dioxide (CO ₂)	1
Methane (CH ₄)	25
Nitrous Oxide (N ₂ O)	298
Sulphur Hexafluoride (SF ₆)	22,200
Perfluorocarbons (PFCs)	4,800–9,200
Hydrofluorocarbons (HFCs)	12–12,000

Boundary Of Assessment

Wockhardt Limited is undertaking its operational carbon footprint based on operational control. Therefore, the focus is on areas where Wockhardt Limited has full authority to introduce and implement operating policies.

The GHG Protocol Corporate Standard includes some indication as to what should be included under Scope 3, but there is also a guidance document available titled "Scope 3 Greenhouse Gas Emissions Calculation: Guidance for the Pharmaceutical Industry" from October 2020 available at: <https://pscinitiative.org/resource?resource=779> that identifies a total of 15 scope 3 categories. Table 2 shows how these Scope 3 emissions have been considered by Wockhardt Limited to date.

The guidance notes that ideally all categories should be calculated, but some are more relevant and significant. Therefore, a screening process was undertaken to ensure those of relevance to Wockhardt Limited operations were considered and are recorded in Table 2. The screening process will be undertaken on an annual basis to ensure applicability of the calculations undertaken for Scope 3.

Table 2: Boundaries For The Pharmaceutical Industry For Scope 3

Current Status	Scope 3 Category	Definition
Calculated using supplier survey responses.	PURCHASED GOODS AND SERVICES	Includes all upstream cradle-to-gate emissions from the production of products purchased or acquired by the reporting company in the reporting year.
Calculated for the first time in 2024 report – to be considered when capital goods are purchased in a year (of greater than 20k value)	CAPITAL GOODS	Includes all upstream (i.e., cradle-to-gate) emissions from the production of capital goods purchased or acquired by the reporting company. Capital goods are final products that have an extended life and are used by the company to manufacture a product, provide a service, or sell, store, and deliver merchandise.
Included in Scope 1 calculations	FUEL AND ENERGY - RELATED ACTIVITIES	Includes the emissions of the extraction, production, and transportation of fuels and energy purchased by the reporting company in the reporting year.
Mileage calculations done	UPSTREAM TRANSPORTATION AND DISTRIBUTION	Includes emissions from the transportation and distribution of products purchased by the reporting company in vehicles/facilities not owned or operated by the reporting company.
Waste data included	WASTE GENERATED IN OPERATIONS	Includes emissions from third-party disposal and treatment of waste that is generated in the company's owned or controlled operations. This category includes emissions from disposal of both solid waste and wastewater. Only waste treatment in facilities owned or operated by third parties is included in scope 3.

Wockhardt Limited Carbon Reduction Plan – March 2025

Current Status	Scope 3 Category	Definition
Car and flights included (train to do in 2026)	BUSINESS TRAVEL	Includes emissions from the transportation of employees for business-related activities in vehicles owned or operated by third parties, such as aircrafts, trains, buses, and passenger cars.
Initial calculation on averages	EMPLOYEE COMMUTING	Includes emissions from the transportation of employees between their homes and their worksites. Emissions may arise from automobile travel, bus travel, rail travel, air travel (if any) or other modes of transportation.
Not applicable to Wockhardt Limited at this time	UPSTREAM LEASED ASSETS	Includes emissions from the operation of assets that are leased by the company and not already included in the company's scope 1 or scope 2 inventories.
Distribution hub and on initial consideration	DOWNSTREAM TRANSPORTATION AND DISTRIBUTION	Includes emissions from transportation and distribution of products sold by the reporting company between the company's operation and the end consumer, if not paid for by the reporting company, in vehicles and facilities not owned or controlled by the reporting company.
Not applicable to Wockhardt Limited at this time	PROCESSING OF SOLD PRODUCTS	Includes emissions from processing of intermediate products by third parties (e.g., manufacturers) after sale by the reporting company.
Not applicable to Wockhardt Limited at this time	USE OF SOLD PRODUCTS	Includes emissions from the use of goods and services sold by the reporting company in the reporting year. The scope 3 emissions from use of sold products include at least the scope 1 and 2 emissions of end users.
Not applicable (assume no waste) to Wockhardt Limited at this time	END OF LIFE TREATMENT OF SOLD PRODUCTS	Includes emissions from the waste disposal and the treatment of all products sold by the reporting company at the end of their life, during the reporting year.
Not applicable to Wockhardt Limited at this time	DOWNSTREAM LEASED ASSETS	This category is applicable to lessors, i.e., companies that receive payments from lessees. This category includes emissions from the operation of assets that are owned by the reporting company, acting as lessor, and leased to other entities in the reporting year that are not already included in scope 1 or scope 2.
Not applicable to Wockhardt Limited at this time	FRANCHISES	This category includes emissions from the operation of franchises not included in scope 1 or scope 2. A franchise is a business operating under a license to sell or distribute another company's goods or services within a certain location.
Pension considerations to be investigated	INVESTMENTS	Includes emissions associated with the reporting company's investments in the reporting year, not already included in scope 1 or scope 2. This category is mostly applicable to investors, i.e. companies that make an investment with the objective of making a profit, and companies that provide financial services.

Table 3: NHS Scope 3 Categories

Scope 3 Category	Category Description	Minimum Boundary	Wockhardt Calculation
Upstream transportation and distribution	Transportation and distribution of products purchased by the reporting company in the reporting year between a company's tier 1 suppliers and its own operations (in vehicles and facilities not owned or controlled by the reporting company) Transportation and distribution services purchased by the reporting company in the reporting year, including inbound logistics, outbound logistics (e.g., of sold products), and transportation and distribution between a company's own facilities (in vehicles and facilities not owned or controlled by the reporting company)	The scope 1 and scope 2 emissions of transportation and distribution providers that occur during use of vehicles and facilities (e.g., from energy use) Optional: The life cycle emissions associated with manufacturing vehicles, facilities, or infrastructure	Miles and km travelled by supplier goods Does not include sea freight – to be calculated in 2026
Waste generated in operations	Disposal and treatment of waste generated in the reporting company's operations in the reporting year (in facilities not owned or controlled by the reporting company)	The scope 1 and scope 2 emissions of waste management suppliers that occur during disposal or treatment Optional: Emissions from transportation of waste	Data from 2 waste companies provided
Business travel	Transportation of employees for business related activities during the reporting year (in vehicles not owned or operated by the reporting company)	The scope 1 and scope 2 emissions of transportation carriers that occur during use of vehicles (e.g., from energy use) Optional: The life cycle emissions associated with manufacturing vehicles or infrastructure	Company car Own car for business purposes Flights Hotels included Train travel to be calculated from 2026 onwards
Employee commuting	Transportation of employees between their homes and their worksites during the reporting year (in vehicles not owned or operated by the reporting company)	The scope 1 and scope 2 emissions of employees and transportation providers that occur during use of vehicles (e.g., from energy use) Optional: Emissions from employee teleworking	Mileage calculated based on number of staff and distance travelled for a year
Downstream transportation and distribution	Transportation and distribution of products sold by the reporting company in the reporting year between the reporting company's operations and the end consumer (if not paid for by the reporting company)	The scope 1 and scope 2 emissions of transportation providers, distributors, and retailers that occur during use	Transportation to distribution hub (3 in

Scope 3 Category	Category Description	Minimum Boundary	Wockhardt Calculation
	company), including retail and storage (in vehicles and facilities not owned or controlled by the reporting company)	of vehicles and facilities (e.g., from energy use) Optional: The life cycle emissions associated with manufacturing vehicles, facilities, or infrastructure	total) have been calculated

Wockhardt Limited Carbon Reduction Plan – March 2025

Scope 1 And 2 Assessment

Wockhardt Limited has been calculating its energy usage in terms of Scope 1 and 2 since 2018. The baseline year considered for Scope 1 and 2 will be 2021. This is because there was an interruption to normal operating procedures during 2020 and then Covid vaccine production requirements were introduced from 2021.

Background

At present, the information available is focused on the main site, where there are 3 significant energy uses:

1. Production consisting of filling, inspecting, and packaging of sterile injectable products.
2. Analytical laboratories where the incoming, intermediate, and finished product testing of all products manufactured and distributed is performed.
3. Storage of raw material, intermediate, and finished goods at specific temperatures: frozen, chilled, and room temperature.

The site has six separate buildings. At the main site, significant energy use is considered to take place within building 4. Then, at some reduced level, buildings 3 and 5. There are two significant utilities: mains natural gas and electricity. Natural gas is supplied directly to 2 and 4. Electricity is used in all six buildings, and there is only the potential to sub-meter building 5.

The rest of the facility is made up of a variety of office-based departments that support the business in a number of ways.

The following are factors that are likely to impact energy usage:

1. Product mix
2. Downtime
3. Working hours and shift patterns
4. Workforce numbers

The organization now operates two business streams:

1. Vaccine
2. CP Hospital products

1. The validation and commissioning activities associated with the combi line to be used for manufacture, previously unused.
2. The installation, commissioning, and qualification and placing into beneficial use of the chiller compound located at the rear of building.
3. The installation, commissioning, and qualification of a frozen storage and freeze thaw processing area for the vaccine; this includes 21 freezers and 3 freeze thaw units.

Methodology

Scope 1 and 2 calculations for the Wrexham site of Wockhardt Limited are currently based on meter readings. The data moving forward will be checked, verified, and audited from the invoices. This data is provided on a weekly basis; however, the monthly totals are used for the purposes of this exercise, and this calculation will be audited and verified.

This method of reporting is considered an accurate measure of the fuels used, as they are mains supplied; there is no reason to consider ullages or losses.

The following fuels have been considered significant:

1. Natural Gas
2. Electricity

The following have been considered direct emissions that are insignificant:

1. Process gas for the sealing of ampoules
2. Boiler stack emissions
3. Process gas for the use of the laboratory

Please see exclusions for justification.

There are a number of other items that will be considered as fugitive and assessed accordingly.

1. Fire extinguishers
2. Air conditioning and chilling plant
3. Diesel generators
4. Lubricants and oils
5. Leaks

There is a separate energy efficiency report that goes into greater detail on Scope 1 and 2 emissions.

Results

For the purposes of this report, vaccine production did not come into effect until 2021, although modifications to storage and the workforce began in 2020, which will have had some potential impact. Changes in preparation for the vaccine included:

Short Term Goals

Impact and aspect assessment has identified energy as a significant opportunity:

- Wockhardt Limited have identified a cross-functional team comprising representation from engineering, environmental, health and safety, and finance to assess and review energy data.
- GHG data has been prepared for the past four years; however, the scope of the business substantially changed during COVID vaccine manufacture 2020 to 2022.
- An analysis of the current data highlights the need to increase the dedicated monitoring of the higher use of two of the buildings and further identify load and usage across all users.
- A system of monitoring is being procured and its positioning developed. This data will be reviewed Q3/4 2024.
- ESOS phase three audit February 23. Full assessment and implementation plan of action based on recommendations change to reporting structure of ESOS.
- ISO14001 Gap Analysis audit completed and actions implemented.
- Perform an external baseline energy review on-site to identify efficiency savings including consideration of PIR lighting, inverter drives, slow or out-of-hours running conditions based on recommendations.
- All departments have been challenged to reduce energy e.g. printing, turning off lighting, and electrical items.
- All employees have had environmental awareness training.
- All employees are encouraged to report environmental initiatives via the reporting app.
- Approx 7% improvement noted in 2023, slightly below the requirement of 10%.

Conclusion

Wockhardt Limited has measured its Scope 1 and 2 performance since 2018. The baseline is set at 2021 due to operational changes that introduction of the vaccination manufacture program caused from 2021. The Scope 3 emissions have a baseline of 2024. Scope 3 calculations have been completed using Defra emission factors from 2025. There are some assumptions and average data that have been used and will be improved on during 2026. It is expected that Scope 3 emissions may increase as data certainty improves. Wockhardt Limited note the need for product carbon footprints to be available by 2028 for the NHS and have a contractor who has access to life cycle software and database licenses, such as Ecoinvent, to ensure that the carbon reduction plan will proceed in a holistic manner covering operational and product requirements.

Calculations have been completed using Defra emission factors for the year assessed. Checks will be made on an ongoing basis on the calculation method and ensure generation as well as aspects such as transmission and distribution are included.

Short-Term Improvement Goal To Achieve A Reduction Of 10% For 2025/6 For Scope 1 And 2 Combined

Long Term Goals

- Ensure energy efficiency is included as a consideration in all new facility, processes, and equipment projects.
- Consider the use of solar energy, working with a consultant company to provide the site with a sustainable energy source by 2025.

Long-term improvement goals to achieve a site carbon footprint reduction of 30% by 2026.

All targets to be reviewed Dec 2025 following further investigations.

Scope 3

Upstream transportation

- Review of the supplier's location and transport distance, opportunities for change limited. Review of supplier's sustainability performance to be assessed.

Commuting

- Review of employee's travel distances, needs to be further assessed based on working from home and shift patterns.
- Review data based on other transport modes.
- Encourage car sharing via engage app.
- Encourage cycling to work via engage app.

Waste

- The site has previously conducted waste stream evaluations and continues to aim to be zero to landfill.
- Review of locations of service providers to reduce transport distances.
- Review of all waste streams for reduction potential.

Business Travel

- Review of business travel performed; more data required for more accurate collection for 2026.

APPENDIX OVERVIEW

Appendix	Details
Appendix 1	Assurance Certificate and Uk Carbon Reduction Report
Appendix 2	Energy Conservation & Technology Absorption at Wockhardt Ltd FY 2025-2026
Appendix 3	Renewable Energy Certificates
	- Renewable Energy Certificate
Appendix 4	ISO Certificates
	- ISO Certificates
Appendix 5	Rain Water Harvesting Certificate
Appendix 6	Waste Management Certificates
	- Packaging Waste Recovery
	- E-Waste Certificate
	- Packaging full producer verification form
	- ENV-007- Waste Disposal
Appendix 7	Quality Assurance Certificates (GMP)
	- Biotech API Certificates
	- Daman Bhimpore
	- Daman Kadaiya
	- Ankleshwar
	- GMP Certificates
	- Pinewood Certificates
	- GDP Certificates

APPENDIX 1:

Assurance Certificate And UK Carbon Reduction Report



INDEPENDENT ASSURANCE STATEMENT

Independent Assurance Statement to Wockhardt Limited on its BRSR Core Report for the FY 2025-26

The Board of Directors,

Wockhardt Limited,

Wockhardt Towers, Bandra Kurla Complex,
Bandra (East), Mumbai 400 051, Maharashtra, India.

Nature of the Assurance

SGS India Private Limited (hereinafter referred to as 'SGS India') was engaged by Wockhardt Limited (the 'Company') to conduct an independent assurance of the Company's Business Responsibility and Sustainability Reporting (BRSR) (the 'Core Report') for the reporting period of April 1, 2025, to March 31, 2026. SGS India has conducted a Reasonable level of Assurance for the BRSR core indicators. This assurance engagement was conducted in accordance with International Standard on Assurance Engagements (ISAE) 3000 (Revised) and ISAE 3410.

Reporting Framework

The Report has been prepared following

1. Master Circular for compliance with the provisions of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015 by listed entities: BRSR Core and Non-Core Framework for Assurance and ESG Disclosures for Value Chain (Circular No. HO/49/14/14(7)2025-CFD-POD2/I/3762/2026), dated 30 January 2026.
2. Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard.
3. ISO 14064-1:2018 Standard.

Intended Users of this Assurance Statement

This Assurance Statement is provided with the intention of informing all Wockhardt Limited internal and external Stakeholders.

Responsibilities

The information in the report and its presentation is the responsibility of the management of the Company. SGS India has not been involved in the preparation of any of the material included in the report.

Our responsibility is to express an opinion on the text, data, and statements within the defined scope of assurance, aiming to inform the management of the Company, and in alignment with the agreed terms of reference. We do not accept or assume any responsibility beyond this specific scope. The Statement shall not be used for interpreting the overall performance of the Company, except for the aspects explicitly mentioned within the scope.

Assurance Standard

SGS has conducted a Reasonable level of Assurance for BRSR core parameters under 9 ESG Attributes, including all essential indicators as specified under BRSR standards and amendments made as on date. This engagement was performed in accordance with the International Standard on Assurance Engagement (ISAE) 3000 (revised) and ISAE 3410 (Assurance Engagements other than Audits or Reviews of Historical Financial Information).

Our evidence-gathering procedures were designed to obtain a 'Reasonable' level of assurance, which is a high level of assurance



in accordance with ISAE 3000(revised) standard, but is not absolute certainty. It involves obtaining sufficient appropriate evidence to support the conclusion that the information presented in the report is fairly stated and is free from material misstatements.

Statement of Independence and Competence

The SGS Group of companies is the world leader in inspection, testing, and assurance, operating in more than 140 countries and providing services including management systems and service certification; quality, environmental, social, and ethical auditing and training; and environmental, social, and sustainability report assurance. SGS India affirms our independence from Wockhardt Limited, being free from bias and conflicts of interest with the organization, its subsidiaries, and stakeholders.

The assurance team was assembled based on their knowledge, experience, and qualifications for this assignment, and comprised auditors registered with ISO 26000, ISO 20121, ISO 50001, SA8000, RBA, QMS, EMS, SMS, GPMS, CFP, WFP, GHG Verification, and GHG Validation Lead Auditors, and experience on the SRA Assurance.

Scope of Assurance

The assurance process involved assessing the quality, accuracy, and reliability of BRSR Indicators, including all KPIs within the report, for the period from April 1, 2025, to March 31, 2026. The reporting scope and boundaries include Wockhardt Limited office, Shendra Manufacturing Facility, Biotech Park Facility, R&D Facility, Ankleshwar Facility, Daman Bhimpore Facility, Daman Kadaiya Facility within India.

Assurance Methodology

The assurance comprised a combination of desktop review, interactions with key personnel involved in developing the report, on-site visits, and remote data verification. Specifically, SGS India undertook the following activities:

- Assessment of the suitability of the applicable criteria in terms of their comprehensiveness, reliability, and accuracy.
- Interaction with key personnel responsible for collecting, consolidating, and calculating the BRSR core and essential indicators, and assessing the internal control mechanisms in place to ensure data quality.
- Application of analytical procedures and verification of documents on a sample basis for the compilation and reporting of the KPIs.
- Assessing the aggregation process of data at the Head Office level.
- Critical review of the report regarding the plausibility and consistency of qualitative and quantitative information related to the KPIs.

Limitations

SGS India did not come across any limitation to the agreed scope of the assurance engagement. SGS India verified data on a sample basis; the responsibility for the authenticity of the data entirely lies with the Company. The assurance scope excluded forward-looking statements, product- or service-related information, external information sources, and expert opinions. SGS India has not been involved in the evaluation or assessment of any financial data/performance of the company. Our opinion on financial indicators is based on the third-party financial reports audited by the Company. SGS India does not take any responsibility for the financial data reported in the audited financial reports of the Company.

The assurance scope excludes:

- Disclosures other than those mentioned in the assurance scope.
- Data reviews outside the operational sites as mentioned in the reporting boundary.
- Validation of any data and information other than those presented in “Findings and Conclusions.”
- The assurance engagement considers an uncertainty of $\pm 5\%$ based on the materiality threshold for Assumption/estimation/measurement errors and omissions.
- The Company's statements that describe the expression of opinion, belief, aspiration, expectation, aim to future intention provided by the Company, and assertions related to Intellectual Property Rights and other competitive issues.
- Mapping of the Report with reporting frameworks other than those mentioned in the Reporting Criteria above.

Findings and Conclusions

Based on the procedures we have performed and the evidence we have obtained, we are satisfied that the information presented by the Company in its report (as per the table below) is complete, accurate, reliable, fairly stated in all material respects, and is prepared in line with the BRSR requirements.

The list of BRSR Core Indicators that were verified within this assurance engagement is given below:

Sr.No.	BRSR Core Attribute	BRSR Core Indicator
1	Greenhouse gas (GHG) footprint	≈ Total scope 1 emissions ≈ Total scope 2 emissions ≈ GHG emission intensity (scope 1 +2)
2	Water footprint	≈ Total water consumption ≈ Water consumption intensity ≈ Water discharge by destination and levels of treatment
3	Energy footprint	≈ Total energy consumed ≈ % of energy consumed from renewable sources ≈ Energy intensity
4	Embracing circularity	≈ Plastic waste ≈ E-waste ≈ Bio medical waste ≈ Construction and demolition waste ≈ Battery waste ≈ Radioactive waste ≈ Other hazardous waste ≈ Other non-hazardous waste ≈ Total waste generated ≈ Waste intensity ≈ Each category of waste generated, total waste recovered through recycling, re-using or other recovery operations. ≈ For each category of waste generated, the total waste disposed of by the nature of the disposal method
5	Employee well-being and safety	≈ Spending on measures towards the well-being of employees as a % of the total revenue of the Company ≈ Details of safety-related incidents for employees
6	Enabling gender diversity in business	≈ Gross wages paid to females as % of wages paid. ≈ Complaints on POSH
7	Enabling inclusive development	≈ Input material sourced from MSMEs/ small producers as % of total purchases. ≈ Job creation in smaller towns: Wages paid to people employed in smaller towns as % of total wage cost
8	Fairness in engaging with customers and suppliers	≈ Instances involving loss/breach of data of customers as a percentage of total data breaches or cybersecurity events. ≈ Number of days of accounts payable
9	Openness of business	≈ Concentration of purchases & sales done with trading houses, dealers, and related parties ≈ Loans and advances & investments with related parties

For and on behalf of SGS India Private Limited

 Kalpesh Thombare Technical Reviewer and National Manager – ESG & Sustainability Services, SGS India. 26th June 2026.	 Chirag Bafna Lead Verifier and Senior Technical Associate – ESG & Sustainability Services, SGS India. Team Member: Ms. Vaibhavi Kulkarni (Technical Associate) 26th June 2026.
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GHG Assurance Statement

Wockhardt Limited

Wockhardt Towers, Bandra Kurla Complex,
Bandra (East), Mumbai 400 051, Maharashtra, India.

SGS India Private Limited (hereinafter referred to as SGS India) was contracted by Wockhardt Limited (the 'Company') to conduct an independent assurance of its annual Greenhouse Gas (GHG) inventory for Scope 1, Scope 2, and Scope 3 pertaining to the reporting period of 01st April 2025 to 31st March 2026. The Company has developed its GHG inventory in accordance with the GHG Protocol Corporate Accounting and Reporting Standard and ISO 14064-1 standard. SGS India has conducted Reasonable Level Assurance for Scope 1 and Scope 2 and Limited Level Assurance for Scope 3 Data. This assurance engagement was conducted in accordance with the "International Standard on Assurance Engagements (ISAE) 3410".

SGS India verified the following parameters given in the Table below:

Scope 1, Scope 2, and Scope 3 Data

Scope	Actual emission (tCo2)
Scope 1 GHG emissions in metric tons of CO2 eq	10430.89
Scope 2 GHG emissions in metric tons of CO2 eq	49637.06
Scope 3 GHG emissions in metric tons of CO2 eq	10319.93

Verification Statement no: BA_ESG_2397879_GHG_V1
Statement Date: 26th June 2026.

This Statement is issued, on behalf of Client, by SGS India ("SGS") under its General Conditions for ESG Assurance Services. A full copy of this statement may be consulted at SGS India. This Statement does not relieve Client from compliance with any regulations that applied to it. Stipulations to the contrary are not binding on SGS and therefore SGS shall have no responsibility vis-à-vis parties other than its Client.

This Statement is not valid without the full verification scope, objectives, criteria and findings available on the Statement.



INDEPENDENT ASSURANCE STATEMENT

Independent Assurance Statement to Wockhardt Limited on its GHG Inventory for FY 2025-26

The Board of Directors,

Wockhardt Limited

Wockhardt Towers, Bandra Kurla Complex,
Bandra (East), Mumbai 400 051, Maharashtra, India.

Nature of the Assurance

SGS India Private Limited (hereinafter referred to as SGS India) was contracted by Wockhardt Limited (the 'Company') to conduct an independent assurance of its annual Greenhouse Gas (GHG) inventory for Scope 1, Scope 2, and Scope 3 pertaining to the reporting period of 01st April 2025 to 31st March 2026. The Company has developed its GHG inventory in accordance with the GHG Protocol Corporate Accounting and Reporting Standard and ISO 14064-1 standard. SGS India has conducted Reasonable Level Assurance for Scope 1, and Scope 2, and Limited Level Assurance for Scope 3 data. This assurance engagement was conducted in accordance with the "International Standard on Assurance Engagements (ISAE) 3410".

Intended Users of this Assurance Statement

This Assurance Statement is provided with the intention of informing all Wockhardt Limited's Stakeholders.

Responsibilities

The information in the report and its presentation are the responsibility of the management of the Company. SGS India has not been involved in the preparation of any of the material included in the report.

Our responsibility is to express an opinion on the text, data, calculation, and statements within the defined scope of verification, aiming to inform the Management of the Company, and in alignment with the agreed terms of reference. We do not accept or assume any responsibility beyond this specific purpose, and it is not intended for use in interpreting the overall performance of the Company, except for the aspects explicitly mentioned within the scope. The Company holds the responsibility for preparing and ensuring the fair representation of the verification scope.

Assurance Standard

SGS India has conducted Reasonable Level Assurance for Scope 1 & Scope 2, and Limited Level Assurance for Scope 3 data. This engagement was performed in accordance with the International Standard on Assurance Engagement (ISAE) 3410. Our evidence-gathering procedures were designed to obtain a 'Reasonable Level of assurance', which involves the underlying assumption that the control environment and controls are reliable.

Statement of Independence and Competence

The SGS Group of companies is the world leader in inspection, testing and assurance, operating in more than 140 countries and providing services including management systems and service certification; quality, environmental, social and ethical auditing and training; environmental, social and sustainability report assurance. SGS affirm our independence from Wockhardt Limited, being free from bias and conflicts of interest with the organization, its subsidiaries and stakeholders.

The assurance team was assembled based on their knowledge, experience and qualifications for this assignment, and

comprised auditors registered with ISO 26000, ISO 20121, ISO 50001, SA8000, RBA, QMS, EMS, SMS, GPMS, CFP, WFP, GHG Verification and GHG Validation Lead Auditors and experience on the SRA Assurance.

Scope of Assurance

The assurance exercise included the evaluation of quality, accuracy, and reliability of the GHG Inventory on Scope 1, Scope 2 and Scope 3 data for the period 01st April 2025 to 31st March 2026.

The scope of verification covers the following aspects:

The reporting scope and boundaries include Wockhardt Limited office, Shendra Manufacturing Facility, Biotech Park Facility, R&D Facility, Ankleshwar Facility, Daman Bhimpore Facility, Daman Kadaiya Facility within India.

Assurance Methodology

The assurance comprised a combination of pre-assurance research, interaction with the key personnel engaged in the process of developing the company's GHG inventory, on-site visits, and remote desk review & verification of data. Specifically, SGS India executed the following activities:

- Interaction with key personnel from the head office and selected manufacturing locations to understand and review the current processes in place for developing the Company's GHG inventory.
- Assessment of internal control mechanism to ensure the reliability and accuracy of emission data.
- Review of the data management system used for collection and consolidation of emission data.
- Review of consistency of data/information within the GHG inventory and between the inventory and source.
- Evaluation of the appropriateness of the quantification methods used to arrive at Scope 1, Scope 2, and Scope 3 emissions with respect to the specific requirements of the GHG Protocol.
- Assurance of emission data on a sample basis, including conversion factors and emissions factors.

Limitations

The assurance scope excludes:

- Disclosures other than those mentioned in the assurance scope.
- Data review outside the operational sites as mentioned in the reporting boundary.
- Validation of any data and information other than those presented in "Findings and Conclusion."
- The assurance engagement considers an uncertainty of $\pm 3\%$ based on materiality threshold for Assumption/estimation/measurement errors and omissions.
- The Company's statements that describe the expression of opinion, belief, aspiration, expectation, aim to future intention provided by the Company, and assertions related to Intellectual Property Rights and other competitive issues.
- Strategy and other related linkages expressed in the Report.
- Mapping of the Report with reporting frameworks other than those mentioned in Reporting Criteria above.

SGS India verified data on a sample basis; the responsibility for the authenticity of data entirely lies with the Company. The assurance scope excluded forward-looking statements, product- or service-related information, external information sources and expert opinions.

Findings and Conclusions

Scope 1, Scope 2 and Scope 3 inventory:

Based on the procedures we have performed and the evidence we have obtained, nothing has come to our attention that causes us to believe that the information presented by the Company in its GHG Inventory report is not prepared, in all material respects, in accordance with the reporting criteria.

SGS India verified the following parameters given in the Table below:

Scope 1, Scope 2 and Scope 3 Data:

Description	FY 2025-26
Scope 1: Direct carbon emissions from owned/controlled operations- Unit-tCO₂Eq	
a. Direct emissions from stationary combustion	4613.55
b. Direct emissions from mobile combustion	38.20
c. Direct emissions from fugitive consumption	5679.77
d. Direct emissions from process consumption	99.38
Scope 1 Total Emission	10430.89
Scope 2: Indirect carbon emissions- Unit-tCO₂Eq	
a. Indirect emissions from purchased/acquired electricity	49,637.06
Scope 2 Total Emission	49,637.06
Scope 3: Indirect carbon emissions- Unit-tCO₂Eq	
Category 1: Purchased goods and services	223.30
Category 5: Waste generated in operations	1.84
Category 9: Downstream Transportation and Distribution	10094.79
Scope 3 Total Emission	10319.93

For and on behalf of SGS India Private Limited

 Kalpesh Thombare Technical Reviewer and National Manager – ESG & Sustainability Services, SGS India. 26 th June 2026.	 Chirag Bafna Lead Verifier and Senior Technical Associate – ESG & Sustainability Services, SGS India. Team Member: Ms. Vaibhavi Kulkarni (Technical Associate) 26 th June 2026.
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INDEPENDENT LIMITED ASSURANCE STATEMENT

Independent Limited Assurance Statement to Wockhardt Limited on its Sustainability Report for FY 2025-26

The Board of Directors,

Wockhardt Limited

Wockhardt Towers, Bandra Kurla Complex,
Bandra (East), Mumbai 400 051, Maharashtra, India.

Nature of the Assurance

SGS India Private Limited (hereinafter referred to as 'SGS India') was engaged by Wockhardt Limited (the 'Company') to conduct an independent assurance of the disclosures under the Sustainability Report (the 'Report') pertaining to the reporting period of April 1, 2025, to March 31, 2026. The Sustainability Report has been prepared in line with the Global Reporting Initiatives (GRI) Standards. This Limited level of assurance engagement was conducted in accordance with International Standard on Assurance Engagements (ISAE) 3000 (Revised) and Assurance Engagements on Greenhouse Gas Statements 3410 and GRI principles.

Intended Users of this Assurance Statement

This Assurance Statement is provided with the intention of informing all Wockhardt Limited's Stakeholders.

Responsibilities

The information in the report and its presentation are the responsibility of the management of the Company. SGS India has not been involved in the preparation of any of the material included in the report.

Our responsibility is to express an opinion on the text, data, and statements within the defined scope of assurance, aiming to inform the management of the Company, and in alignment with the agreed terms of reference. We do not accept or assume any responsibility beyond this specific scope. The Statement shall not be used for interpreting the overall performance of the Company, except for the aspects explicitly mentioned within the scope. The Company holds the responsibility for preparing and ensuring the fair representation of the assurance scope.

Assurance Standard

SGS has conducted a Limited level Assurance engagement in accordance with the International Standard on Assurance Engagement (ISAE) 3000 (Assurance Engagements other than Audits or Reviews of Historical Financial Information), Assurance Engagements on Greenhouse Gas Statements 3410 and GRI principles. Our evidence-gathering procedures were designed to obtain a '*Limited level of assurance*'. The procedures performed in a limited assurance engagement are designed to support expectations regarding the direction of trends, relationships and ratios rather than to identify misstatements with the level of precision expected in a reasonable assurance engagement.

Statement of Independence and Competence

The SGS Group of companies is the world leader in inspection, testing and assurance, operating in more than 140 countries and providing services including management systems and service certification; quality, environmental, social and ethical auditing and training; environmental, social and sustainability report assurance. SGS affirms our independence from Wockhardt Limited, being free from bias and conflicts of interest with the organisation, its subsidiaries and stakeholders.

The assurance team was assembled based on their knowledge, experience and qualifications for this assignment, and comprised auditors registered with ISO 26000, ISO 20121, ISO 50001, SA8000, RBA, QMS, EMS, SMS, GPMS, CFP, WFP,

GHG Verification and GHG Validation Lead Auditors and experience on the SRA Assurance

Scope of Assurance

The assurance process involved assessing the quality, accuracy, and reliability of ESG Indicators within the Sustainability report for the period April 1, 2025, to March 31, 2026. The reporting scope and boundaries include Wockhardt Limited, and its regional offices spread across Central, North, East, West and South in the different states of India.

Assurance Methodology

The assurance comprised a combination of desktop review, interaction with the key personnel engaged in the process of developing the report, on-site visits, and remote verification of data. Specifically, SGS India undertook the following activities:

- Assessment of the suitability of the applicable criteria in terms of their comprehensiveness, reliability, and accuracy.
- Interaction with key personnel responsible for collecting, consolidating, and calculating the ESG KPIs and assessing the internal control mechanisms in place to ensure data quality.
- Application of analytical procedures and verification of documents on a sample basis for the compilation and reporting of the KPIs.
- Assessing the data reporting process at the office level and the aggregation process of data at the Head Office level
- Critical review of the report regarding the plausibility and consistency of qualitative and quantitative information related to the KPIs.

Limitations

The assurance scope excludes:

- Disclosures other than those mentioned in the assurance scope.
- Data reviews outside the operational sites as mentioned in the reporting boundary.
- Validation of any data and information other than those presented in “Findings and Conclusions.”
- The assurance engagement considers an uncertainty of $\pm 5\%$ based on the materiality threshold for Assumption/ estimation/measurement errors and omissions.
- The Company's statements that describe the expression of opinion, belief, aspiration, expectation, aim to future intention provided by the Company, and assertions related to Intellectual Property Rights and other competitive issues.
- Strategy and other related linkages expressed in the Report.
- Mapping of the Report with reporting frameworks other than those mentioned in the Reporting Criteria above.

SGS India verified data on a sample basis; the responsibility for the authenticity of data entirely lies with the Company. The assurance scope excluded forward-looking statements, product- or service-related information, external information sources and expert opinions. SGS India has not been involved in the evaluation or assessment of any financial data/performance of the company. Our opinion on financial indicators is based on the third-party audited financial reports of the Company. SGS India does not take any responsibility for the financial data reported in the audited financial reports of the Company.

Findings and Conclusions

Based on the procedures we have performed and the evidence we have obtained, nothing has come to our attention that causes us to believe that ESG KPIs (listed below) presented by the Company in its Sustainability report are not prepared, in all material respects, in accordance with the reporting criteria.

The list of ESG KPIs that were verified within this assurance engagement is given below:

GRI Indices	Description
GRI 201: Economic Performance 2016	
201-1	Proportion of spending on local suppliers
201-3	Defined benefit plan obligations and other retirement plans
201-4	Financial assistance received from the government
GRI 205: Anti-corruption 2016	

205-1	Operations assessed for risks related to corruption
205-2	Communication and training about anti-corruption policies and procedures
205-3	Confirmed incidents of corruption and actions taken
GRI 302: Energy 2016	
302-1	Energy consumption within the organization
302-3	Energy intensity
GRI 303: Water and Effluents 2018	
303-3	Water withdrawal
303-4	Water Discharge
303-5	Water consumption
GRI 305: Emissions 2016	
305-1	Direct (Scope 1) GHG emissions
305-2	Energy indirect (Scope 2) GHG emissions
305-3	Other indirect (Scope 3) GHG emissions
305-4	GHG emissions intensity
305-5	Reduction of GHG emissions
305-7	Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions
GRI 306: Waste 2020	
306-2	Management of significant waste-related impacts
306-3	Waste Generated
306-4	Waste diverted from disposal
306-5	Waste is directed to disposal
GRI 401: Employment 2016	
401-1	New employee hires and employee turnover
401-2	Benefits provided to full-time employees that are not provided to temporary or part-time employees
401-3	Parental leave
GRI 402: Labor/Management Relations 2016	
402-1	Minimum notice periods regarding operational changes
GRI 403: Occupational Health and Safety 2018	
403-1	Occupational health and safety management system
403-2	Hazard identification, risk assessment, and incident investigation
403-3	Occupational health services
403-4	Worker participation, consultation, and communication on occupational health and safety
403-5	Worker training on occupational health and safety
403-6	Promotion of worker health
403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships
403-8	Workers covered by an occupational health and safety management system
403-9	Work-related injuries
403-10	Work-related ill health
GRI 404: Training and Education 2016	
404-1	Average hours of training per year per employee
404-2	Programs for upgrading employee skills and transition assistance programs
GRI 405: Diversity and Equal Opportunity 2016	
405-1	Diversity of governance bodies and employees

GRI 407: Freedom of Association and Collective Bargaining 2016	
407-1	Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk
GRI 408: Child Labour 2016	
408-1	Operations and suppliers are at significant risk of incidents of child labour
GRI 409: Forced or compulsory labor	
409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor
GRI 410: Security Practices 2016	
410-1	Security personnel trained in human rights policies or procedures
GRI 413: Local Communities 2016	
413-1	Operations with local community engagement, impact assessments and development programs
GRI 416: Customer Health and Safety 2016	
416-2	Incidents of non-compliance concerning the health and safety impacts of products and services
GRI 418: Customer Privacy 2016	
418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data

For and on behalf of SGS India Private Limited

 Kalpesh Thombare Technical Reviewer and National Manager – ESG & Sustainability Services, SGS India. 15th July 2026.	 Chirag Bafna Lead Verifier and Senior Technical Associate – ESG & Sustainability Services, SGS India. Team Member: Ms. Vaibhavi Kulkarni (Technical Associate) 15th July 2026.
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CARBON REDUCTION PLAN

Supplier name: ...Wockhardt UK.....

Publication date: ...April 2026.....

Commitment to achieving Net Zero

Wockhardt UK (including all subsidiaries) are committed to achieving Net Zero emissions by 2050.

Baseline Emissions Footprint

Baseline emissions are a record of the greenhouse gases that have been produced in the past and were produced prior to the introduction of any strategies to reduce emissions. Baseline emissions are the reference point against which emissions reduction can be measured.

Baseline Year: 2021 (Scope 1 & 2) 2024 (Scope 3)	
Additional Details relating to the Baseline Emissions calculations.	
Scope 1 and 2 have a base year of 2021 – this takes into account operational changes associated with vaccination production processes. Scope 3 has a base year of 2024 but please note: some aspects of Scope 3 are subject to further development and checking with additional categories and operational areas	
Baseline year emissions:	
EMISSIONS	TOTAL (tCO ₂ e)
Scope 1	1739.6 (2021)
Scope 2	1807.43 (2021)
Scope 3 (Included Sources)	24596.94 (2024)
Total Emissions	28143.97

Current Emissions Reporting

Reporting Year: 2025	
EMISSIONS	TOTAL (tCO ₂ e)
Scope 1	1724.57
Scope 2	42.77
Scope 3 (Included Sources)	23,401.94
Total Emissions	25,169.29 tonnes

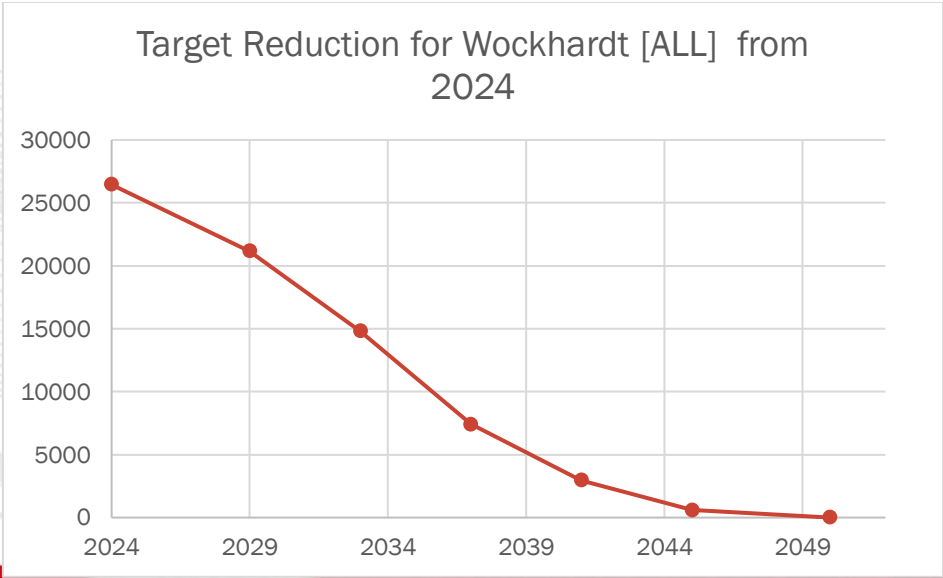
Emissions reduction targets

In order to continue our progress to achieving Net Zero, we have adopted the following carbon reduction targets.

We aim for a 30% reduction of Scope 1 and 2 emissions by 2026.

We project that total carbon emissions must decrease over the next five years to **15,867 tCO₂e** by **2029**. This is a total reduction of **40%**

Progress against these targets can be seen in the graph below:



Carbon Reduction Projects

Completed Carbon Reduction Initiatives

The following environmental management measures and projects have been completed or implemented since the 2021 (Scope 2) base year. The purchase of renewable energy certificates for Scope 2 emissions. The carbon emission reduction achieved by these schemes equate to 1807.4 tCO₂e, a 100%ge reduction against the 2021 base year for Scope 2 and the measures will be in effect when performing the contract.

Use of renewable energy certificates has substantially reduced our Scope 2 emissions. The remaining emissions are limited to Unit 10.

We have continued the process of calculating all our Scope 3 emissions and identified areas where calculation has been improved. The coverage of Scope 3 emissions is considered to be comprehensive and to cover all areas applicable to the business. We use monthly review of data and have senior management support for this important initiative.

We have an environmental management plan that includes key aspects such as switching off redundant equipment and mindful purchase of company vehicles.

In the future we hope to implement further measures such as:

Work on calculation of individual product carbon footprints is on-going in keeping with the NHS target in place of 2028. This questionnaire response is included in our Carbon Reduction Plan that will be maintained to communicate savings and positive measures in place within Wockhardt UK.

Wockhardt UK Carbon Reduction Plan – April 2026

Declaration and Sign Off

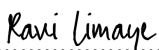
This Carbon Reduction Plan has been completed in accordance with PPN 06/21 and associated guidance and reporting standard for Carbon Reduction Plans.

Emissions have been reported and recorded in accordance with the published reporting standard for Carbon Reduction Plans and the GHG Reporting Protocol corporate standard¹ and uses the appropriate Government emission conversion factors for greenhouse gas company reporting².

Scope 1 and Scope 2 emissions have been reported in accordance with SECR requirements, and the required subset of Scope 3 emissions have been reported in accordance with the published reporting standard for Carbon Reduction Plans and the Corporate Value Chain (Scope 3) Standard³.

This Carbon Reduction Plan has been reviewed and signed off by the board of directors (or equivalent management body).

Signed on behalf of the Supplier:


.....
6BD0DF7AFB3C493...
16-Feb-26

Date:

¹<https://ghgprotocol.org/corporate-standard>
²<https://www.gov.uk/government/collections/government-conversion-factors-for-company-reporting>
³<https://ghgprotocol.org/standards/scope-3-standard>



Document Reference: ENG/2026/CRP-001

Date : 06 August 2026

Pinewood Healthcare Carbon Reduction Plan

Pinewood Healthcare is committed to reducing the Green House Emissions in line with Irish Government approved Climate Action Plan 2025.

Since the year 2022, we have only procured Renewable Electricity from the Grid to service its power demand for both Ballymacarbry and Ballymount sites.

See attached certificate issued by Captured Carbon for Renewable Electricity purchased in the year 2025.

In 2026, we are implementing roof solar system to self-generate renewable solar power on the Ballymacarbry site. The installation is capable of generating 904 kWp power and estimated in further reduction of carbon footprint by 176,783 kg/year.

There is continued emphasis on the site to monitor our energy demands and projects are evaluated on ongoing basis to further reduce our Green House Emissions.

Signature: Nagesh Naik
Nagesh Naik (Aug 6, 2026 16:50:00 GMT+1)
Email: n.naik@pinewood.ie

Name: Nagesh Naik
Designation: Head of Engineering
Address:
Pinewood Healthcare
Ballymacarbry
Co Waterford IE
E91 D434

APPENDIX 2: Energy Conservation & Technology Absorption At Wockhardt Ltd FY 2025 -2026

ANNEXURE VII TO THE BOARD'S REPORT

Energy Conservation, Technology Absorption and Foreign Exchange Earnings and Outgo required under Rule 8 of the Companies (Accounts) Rules, 2014

Your Company operates in a safe and environmentally responsible manner for the long-term benefit of all stakeholders. The Company is committed to take appropriate measures to conserve energy and drive energy efficiency in its operations.

Particulars of Energy Conservation, Technology Absorption and Foreign Exchange Earnings and Outgo required under Rule 8 of the Companies (Accounts) Rules, 2014 are provided below:

(A) CONSERVATION OF ENERGY:

1) The Steps Taken or impact on Conservation of Energy, the Steps taken by the Company for utilizing alternate sources of energy and the Capital investment in energy conservation equipments:

ANKLESHWAR

1. The power factor maintained 0.996 (requirement 0.95 above), which leads to saving of ₹ 9.87 Lakh.
2. 40 Watt LED light fixtures replaced in place of old HPMV lamps which leads to saving 0.12 KWH per fixture (Total 231 LED fixtures replaced in financial year 2025-2026 total saving per annum energy units saved 9979 KWH leading to saving of to ₹ 10.15 Lakh)
3. Changeover of utility from Chilled brine to chilled water to stop chilled brine compressor energy units saved 12798 KWH leading to saving of to ₹ 33.15 Lakh.
4. Initiated to maintain the Dissolved Oxygen in aeration, installed CCox Agitator in July, 2025 and from August, 2025 to March, 2026 power and fuel saved leading to saving of ₹ 60 Lakh.
5. ETP MEE plant ATFD rotor assembly with blade modification done due to this arrangement eliminate the recirculation of liquid salt from ATFD to MEE, annual power and steam saved amounting to ₹ 14.55 Lakh.

DAMAN

HVAC system

1. VFD installed in cooling water fan and interlocking done with inline temperature transmitter and achieved electrical unit saving by 6%. Energy Units saved 55874 KWH per year, saved amount ₹ 3.35 Lakh.
2. Installation of VFD in AC store III & IV to run AHU at reduced RPM and minimum required ACPH to save electricity also maintain temperature and RH as per design and user requirement. Energy Units saved in AC Store III and AC store IV area saved 51960 KWH per Year amount saved ₹ 3.18 Lakh per year.
3. For AHU modification for chiller plant shutdown on weekly off days
 - I. Modification of 24 X 7 running AHU on DX to stop chiller plant, Cooling tower with Pump, Brine pump and condenser pump on non-productive hour and weekly off days for Incubator Room, Stability chamber and sample area AHU.
 - II. Heater has been replaced with hot gas coil to avoid chiller operation on weekly day and holiday. Total Electric units saved 197164 KWH per year amounting to ₹ 11.82 Lakh per year.
4. AHU condensate water has been used in the cooling tower water instead of raw water and saved ₹ 0.29 Lakh per year.

Water System area

1. Pre - treatment (high efficiency RO plant) to be installed after the borewell to reduce hardness and TDS of water prior to main storage tank, used for water purification system which is help to reduction in Water Tanker, saved water 15072 KL and saved ₹ 20.09 Lakh also reduction in softener regeneration and saved ₹ 3.58 Lakh and resulting in total saving of ₹ 23.67 Lakh.
2. Developed system for rain water collection to use in monsoon period (almost four months of every year plant run on rain water only. No need of water procurement. saved 3.33 KL water and amount saved ₹ 0.41 Lakh for 4 months in a year.
3. Purified rejected water used cooling tower and boiler instead of soft water also RO and UF water used for gardening and wash room (raw water) purpose, saved water 7767 KL and amounting to ₹ 9.71 Lakh.

Utility area

1. Utilized low capacity 35 CFM air compressor in Bhimpore Plant for water system in place of 505 CFM air Compressor on plant off days and Holidays and saving by consumption, saved energy units 45915 KWH amounting to ₹ 3.88 Lakh.
2. Utilized low capacity 35 CFM air compressor in Kadaiya Plant for water system in place of 300 CFM air Compressor on plant off days and Holidays and saving by consumption, saved energy units 45915 KWh amounting to ₹ 2.81 Lakh.
3. Total 116405 KWH solar units generated at Kadaiya plant from April, 2025 to March, 2026 from renewable solar energy.
4. 95% condensate recovery from Boiler and equipment condensate water has been used in Boiler feed water tank to maintained the temperature and saved the water amounting to saving of ₹ 0.7 Lakh per year.

ETP area

1. ETP treated water used for gardening: 15.06 Million Lit/yr. at Bhimpore Plant.
2. ETP treated water used for gardening: 0.825 Million Lit/yr. at Kadaiya Plant.

SHENDRA**1. Chiller Plant Optimization**

Enhanced operational efficiency by improving the specific power consumption from 0.74 to 0.65 kw/TR. This technical optimization resulted in a significant annual saving of ₹ 28 Lakh.

2. ETP Power Reduction via Process Innovation

By transitioning to an aspirator-based aeration system in the Effluent Treatment Plant, daily power consumption was slashed by over 50%, yielding a cost benefit of ₹ 14 Lakh per annum.

3. Zero-Investment Set-Point Calibration

Optimized ambient temperature set-points by a margin of 3°C. This strategic adjustment achieved a saving of 1.68 Lakh units of electricity, valued at ₹ 18 Lakh, with zero capital expenditure.

4. Boiler System & Draft Efficiency

Improved thermal efficiency by right-sizing the Induced Draft fan and reducing ducting length. This initiative lowered annual briquette consumption by 150–180 tons, saving of ₹ 8 Lakh per year.

5. WFI (Water for Injection) Process Optimization

Refined the pressure settings for the Bosch washing machine units, leading to a substantial process-related saving of ₹ 30 Lakh.

6. Water Recovery & Condensate Management

Strengthened the circular water economy by integrating MCDP recycling and increasing condensate recovery to 95%. This reduced raw water dependency, saving ₹ 4.2 Lakh in procurement costs and reclaiming 630 KL of high-grade hot water for reuse.

7. Power Factor Management

Through consistent monitoring and maintaining a near-unity Power Factor, the facility successfully secured ₹ 13 Lakh in utility incentives and efficiency savings.

R & D CENTRE

1. NDD Biology/Toxicology Laboratory, AHU Nos. 04, 06, 09, and 13 are switched off during night hours, from 6:00 p.m. to 8:00 a.m. Electricity savings of ₹ 4.17 Lakh.
2. 100 TR Trane chiller Evaporator and condenser - chemical descaling done to achieve better approach temperature i.e. below 3 Deg. Cel Electricity savings of ₹ 3.15 Lakh.
3. Main R&D building, air compressors of 310 CFM and 150 CFM capacity are switched off during night hours. For biotech fermentation batches, a 50 CFM air compressor is operated.. Electricity savings of ₹ 1.3 Lakh.
4. Formulation and Development lab, AHU No - 3, 24, 25 are switched off and operated as per batches planned in area. Electricity savings of ₹ 9.07 Lakh.
5. LED fixtures have been installed on street light poles in place of sodium vapour lamps. A total quantity of 35 units of 75-watt fixtures have been fitted, resulting in electricity savings of ₹ 0.65 Lakh.
6. Periodical preventive maintenance of transformer, DG set, Air compressor, Chillers, Cooling towers, Split AC units done for better efficiency. Electricity savings of ₹ 1.55 Lakh.
7. Cassette AC - repairing and servicing done with replacement of new control card, blower motors for DRA & AVL department. For better performance of AC units in CPB building. Electricity savings of ₹ 5.61 Lakh.
8. Offices / Laboratory Lights / Air conditioners - Switched off manually, in night period. Electricity savings of ₹ 0.43 Lakh.
9. R&D area three chillers & chilled water pipeline interlocked with each other, Enabling to switch off one Chiller, associated Cooling water pump and CT Fan motor. Electricity savings of ₹ 3.31 Lakh.
10. AHU, Vacuum pump regular Preventive Maintenance done for better efficiency & performance. Electricity savings of ₹ 1.02 Lakh.
11. NDD Biology - Installed - 02 x 1.5 TR Split AC of Blue star make of 5 star rating. Electricity savings of ₹ 0.08 Lakh.
12. Wet Chemistry lab -NCE -Installed - 02 x 1.5 TR Split AC of Blue star make of 5 star rating savings of ₹ 0.10 Lakh.
13. Replaced 2 old ac units with 3 star ac units in IT server room - R&D building. Electricity savings of ₹ 0.25 Lakh.
14. Replaced 2 TR old AC's with new 3 star rated AC's in NCE -AVL. Electricity Savings of ₹ 0.25 Lakh.
15. Replaced 1.5 TR old AC unit with 3 star ac unit in CRL HOD cabin. Electricity Savings of ₹ 0.04 Lakh.
16. APFC panel - Capacitor Bank - periodical preventive maintenance. Improvement in average PF lag 98.95 up to lag 99.93 PF. Electricity savings of ₹ 5.5 Lakh..
17. Annual saving by load management in low tariff slot - TOD (Time of day). Electricity savings of ₹ 6.65 Lakh.

BIOTECH PARK

1. Initiation of condensate recovery from F2 Plant. Reduction in fuel and water Consumption. savings - ₹ 13 Lakh/year
2. Process air & Instrument air leakages rectification in Plant—saving - ₹ 12 Lakh/year
3. Installation of Economizer in old Briequette Boiler.- saving ₹ 12 Lakh/year
4. Chilled water system Insulation repairing—savings ₹ 5 Lakh/year
5. Cooling water pump Modification for energy saving-The cooling tower has Three pumps, in Pump impeller Modification done pump Pump Impeller Trimming done from 410 MM To 370 MM After Pump modification each pump has taken power 55 KW/hour - ₹ 5.25 Lakh.
6. Power Factor (PF) Management - Through consistent monitoring and maintaining a near-unity Power Factor, the facility successfully secured ₹ 20 Lakh in utility incentives and efficiency savings. Also Maintain KWH & KVAH difference is less than 0.2%.
7. Lighting Innovation - Existing light fixture is use & throw we have innovate & retrofit kit used & save new light fixture cost @ ₹ 10 Lakh.
8. DG Set - One of our DG set was failed @ six month, that time we have managed the load on other DG set & reduce rent DG set cost @ ₹ 12 Lakh.

(B) TECHNOLOGY ABSORPTION, ADAPTATION AND INNOVATION:

1. The efforts made towards technology absorption at different manufacturing units

1. New Upgraded SAP System implemented for online activity of preventive maintenance, breakdown, calibration and building maintenance.
2. Auto weighing Dispensing activity through the SAP system implemented.
3. Cartridge Filling yield increased form 94.08% to 96.0 %
4. Vial Filling yield increased form 97.00% to 98.0%
5. Continuous Particle Measurement System (CPMS) and Zwick make Cartridge leak test machine software upgradation work completed.
6. Pack leader Labelling machine for Optical Character Reader system software upgradation work completed for label rejection in pkg.
7. Alternate vendor development - Machine trial of Datwyler bottom plungers on cartridge sourced from India plant & Universal Medicap stopper on Vial line completed & found satisfactory
8. Acoustic enclosure to Diesel Generator (DG) room at Biotech Park reduced the noise with insertion loss of 25 db in DG room made the workplace more comfortable.
9. Replacement of old Blower (twin lobe Blower to energy saving trilobe blower for ETP Aeration tank 40 HP) resulted in 10% energy savings.
10. Pre New Water Chiller resulted in energy savings. Furnace oil (FO) replaced by PNG (Pressurized natural gas) in RBI Boiler resulted in reduced greenhouse gas emission, improved air quality because PNG produces lower concentration of sulphur dioxide, Oxides of nitrogen.
11. New equipment for WCK 5222 sterile plant blend manufacturing for NCE product plant upgradation. Upgradation of Plant for DMP product with glass lined reactor and rubber lined centrifuge and revamping of stability chamber.

2. Imported Technology (imported during the last 3 years reckoned from the beginning of the financial year):

The Company has not imported any technology.

3. The expenditure incurred on Research and Development:

(₹ in Crore)

Particulars	Consolidated	Standalone
Capital	210	321
Revenue	120	125
Total	330	446

(C) FOREIGN EXCHANGE EARNINGS AND OUTGO

During the year, the Foreign Exchange Earnings was ₹988.67 Crore (Previous year ₹715 Crore) and Foreign Exchange Outgo was ₹ 460.3 Crore (Previous year ₹ 220.99 Crore).

For and on behalf of the Board of Directors

Dr. Habil Khorakiwala

Chairman

DIN: 00045608

APPENDIX 3: Renewable Energy Certificates

(Renewable Energy Certificate)

CERTIFICATE OF RENEWABLE ELECTRICITY SUPPLY

This certificate is presented to

PINEWOOD HEALTHCARE LTD

1st JANUARY 2025 – 31st DECEMBER 2025

This certificate confirms that the electricity consumed by the Consuming Company; **PINEWOOD HEALTHCARE LTD**, as a client of Supply Company; **GO Power**, has been verified as being sourced from **100.00%** renewable electricity generation by **Captured Carbon** for the period outlined above.

The renewable electricity generation is verified by certified Renewable Energy Certificates. The locations of consumption are listed in the table below, which forms part of this Certificate and includes **3 MPRN(s)**. This certificate extends across **1 page(s)**.

MPRN	Location
10000081096	BALLYMACARBRY, CLONMEL,
10002442677	UNIT 2, M50 BUSINESS PARK, BALLYMOUNT, DUBLIN 24,
10002442689	UNIT 1, M50 BUSINESS PARK, BALLYMOUNT, DUBLIN 24,



APPENDIX 4: ISO Certificates

N° 2018/79819.3

Page 1 / 1

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification certifie que le système de management mis en place par :

WOCKHARDT LIMITED

for the following activities:
pour les activités suivantes :

MANUFACTURING OF PHARMACEUTICAL FORMULATIONS

has been assessed and found to meet the requirements of:
a été évalué et jugé conforme aux exigences requises par :

ISO 14001:2015

and is developed on the following locations:
et est déployé sur les sites suivants :

PLOT NO. E-1/1, 6-A, MIDC SHENDRA, CHHATRAPATI SAMBHAJINAGAR,
MAHARASHTRA - 431154, INDIA

This certificate is valid from (year/month/day)
Ce certificat est valable à compter du (année/mois/jour)

2024-09-02

Until
jusqu'au

2027-09-01



Ce document est signé électroniquement. Il constitue un original électronique à valeur probatoire.
This document is electronically signed. It stands for an electronic original with probatory value.

Julien NIZRI
Managing Director of AFNOR Certification
Directeur Général d'AFNOR Certification



Scan this QR code to
check the validity of the
certificate.
*Flashez ce QR Code
pour vérifier la validité
du certificat.*

The electronic certificate only, available at www.afnor.org, attests in real-time that the company is certified. *Seul le certificat électronique, consultable sur www.afnor.org, fait foi en temps réel de la certification de l'organisme.* COFRAC accreditation n° 4-0001, Management Systems Certification, Scope available on www.cofrac.fr.
Accréditation COFRAC n° 4-0001, Certification de Systèmes de management, Portée disponible sur www.cofrac.fr.
AFAQ is a registered trademark. AFAQ est une marque déposée. CERTI F 0956.9 - EN 01/2020

N° 2018/79820.5

Page 1 / 1

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification certifie que le système de management mis en place par :

WOCKHARDT LIMITED

for the following activities:
pour les activités suivantes :

MANUFACTURING OF PHARMACEUTICAL FORMULATIONS

has been assessed and found to meet the requirements of:
a été évalué et jugé conforme aux exigences requises par :

ISO 45001:2018

and is developed on the following locations:
et est déployé sur les sites suivants :

**PLOT NO. E-1/1, 6-A, MIDC SHENDRA, CHHATRAPATI SAMBHAJINAGAR,
MAHARASHTRA - 431154, INDIA**

This certificate is valid from (year/month/day)
Ce certificat est valable à compter du (année/mois/jour)

2024-09-02

Until
jusqu'au

2027-09-01



Ce document est signé électroniquement. Il constitue un original électronique à valeur probatoire.
This document is electronically signed. It stands for an electronic original with probatory value.

Julien NIZRI

Managing Director of AFNOR Certification
Directeur Général d'AFNOR Certification



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Certificate IN24/00000540

The management system of

Wockhardt Ltd.

SGS

Biotech Park, H14/2, MIDC, Waluj, Aurangabad - 431136, Maharashtra, India

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design and Development, Manufacture and Distribution of unfilled disposable pens and Reusable Insulin Pens

This certificate is valid from 26 June 2024 until 26 June 2027 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 26 June 2024

Jonathan M. Hall

Authorised by

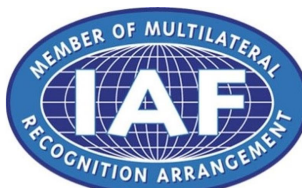
Jonathan Hall

Global Head - Certification
Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com



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Certificate IN25/00000032

The management system of

Wockhardt Limited

SGS

E -1/1, Wockhardt Infrastructure Development Ltd., Special Economic Zone (SEZ), E-1, Shendra MIDC Five Star Industrial Area, Shendra, Chhatrapati Sambhajnagar, Maharashtra - 431154, India

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Manufacture and Distribution of unfilled disposable pens and Reusable Insulin Pens

This certificate is valid from 13 January 2025 until 13 January 2028 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 13 January 2025

L. Moran

Authorised by

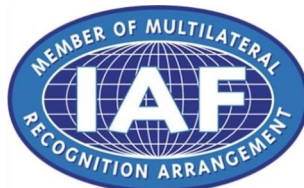
Liz Moran

Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

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APPENDIX 5: Rain Water Harvesting Certificate



Certificate

of KFP (Patented) RWH

This is to certify that
we have implemented 8 nos. of KFP (Patented) RWH Structures

at **Wockhardt Limited (Biotech Park)**

H-14/2, MIDC Area, Waluj, Aurangabad (MH)

and created the capacity to recharge 2.4 Crore Ltr rainwater underground annually

Date: 25 June 2013

for Kedia Rainwater Harvesting Pvt. Ltd.

Rajendra Kedia
Authorised Signatory



APPENDIX 6: Waste Management Certificates

Packaging Waste Recovery

Member No: 100783



CERTIFICATE OF COMPLIANCE

2025

It is hereby certified on behalf of Repak Limited, an approved body for the European Union (Packaging) Regulations 2014, as amended, that

Pinewood Healthcare

is participating in a satisfactory manner in the scheme operated by Repak Limited, for the recovery of packaging and packaging waste and is accordingly exempt from the requirements of regulations 10, 11 and 25 of those Regulations.

This certificate is valid from the date of grant below until the 31st day of December of the same year unless earlier revoked in accordance with the membership rules of the scheme.

Issued on behalf of Repak Limited

A handwritten signature in black ink, appearing to read 'Z. Kavanagh'.

Zoe Kavanagh
Chief Executive Officer, Repak





PERFECT E-WASTE RECYCLERS

Plot No. A-8/1, MIDC, Chikalthana, Aurangabad 431001

Contact No. 9156606777, 8888082022, Email: perfectrecycler@gmail.com



Maharashtra Pollution Control Board
महाराष्ट्र प्रदूषण नियंत्रण बोर्ड

MPCB Consent No :- Format I.0/RO-HQ/UNA No.0000127645/CO/22060000619

Certificate No :- 34

CERTIFICATE OF E-WASTE DISPOSAL



This is to certify that e-waste received for disposal

From

M/s Weckhardt Ltd. (Biotech Park).

H 14/2, Biotech Park MIDC Waly, Waly Aurangabad-431133

has been safely disposed at our registered facility in an environment friendly manner.

We appreciate your effort in contributing to a green Environment.

Weight : 678 Kg.

Date : 26/06/2025



Perfect E-Waste Recyclers

[Signature]

Authorized Signatory

E-Waste Certificate

CERTIFICATE OF RESPONSIBLE RECYCLING

ISSUED TO

WOCKHARDT LTD

This document certifies that E-Incarnation Recycling Private Limited, processes, recycles, destroys and displaces the received material in an environmentally sustainable manner that is in accordance with all local, state and central Government regulations. Further E-Incarnation Recycling Private Limited certifies that all intellectual client data will be destroyed or erased properly from the hard drives and other media.

E-Incarnation Recycling Private Limited assumes ownership, possession, title, responsibility and control of the materials received on 11-01-2020; listed in Section A of this Certification.

Contact: WOCKHARDT TOWERS, BKC, G Block BKC,
BANDRA EAST MUMBAI 400-051

Section A: Materials Received for processing

ERPL Customer Id: 585 Transaction Id: 1089

Materials Received

Quantity

AS PER LIST ATTACHED



Reg. No.: MPCB/RO(HQ)/Reg./15/E-waste/HWMD-258

E-Incarnation Recycling Pvt. Ltd. Mardia House, 96, C. P. Tank Road, Mumbai - 400 004.

Tel - 022 66251300-33. Fax - 022 23877102. E-Mail - recycle@E-Incarnation.com. Web - www.E-Incarnation.com.



1304, Lodha Supremus, Opp. World One, Senapati Bapat Marg, Lower Parel (W), Mumbai - 400 013.

Receipt No. - 1089

Date - 11/01/2020

Received from – **Wockhardt LTD**

Particulars –

Sr. No	Description	Qty
1	IBM TS 3500 Tape Library	1
2	IBM Empty RACK	1
3	IBM X Series 346	1
4	IBM E Series P5	3
5	IBM Storage 146.8 GB x 10	1
6	IBM Storage 146.8 GB x 11	1
7	IBM Storage empty Chassis	1
8	IBM Empty RACK	1
9	IBM X Series 346	1
10	IBM P5 146GB x 3, 142GB x 2, 73GB x2	1
11	IBM x 366 Series 73.4GB x 4	1
12	IBM E Series P5 73GB x 2	4
13	Screen with Keyboard	1
14	IBM E Series P5 73GB x 2	2
15	IBM e Series 146Gb x 3, 73GB x1	1
16	IBM e Server P5 73GB x 6	1
17	IBM e Series P5 73.4 GB x 4	1
18	Empty Rack	1
19	Screen with Keyboard	1
20	IBM X Series 346 73.4 GB x2	1
21	Empty Rack	1
22	Cisco C370 Email Security Appliance	2
23	Dell Power edge 2950 146GB x 2	1
24	Dell Power edge 1950 146GBx2	1
25	Dell Power edge 2950 146GB x 2, 300GB x 2	1
26	Empty Rack	1
27	HP Pro liant DL380 146.8GB x4	1
28	IBM X Series 346 73.4 GB x2	1
29	HP Pro liant DL380 146.8GB x2	1
30	IBM Empty Rack	1

31	IBM System P5 146GBx2	2
32	Screen with Keyboard	1
33	IBM System Storage 146GBx14	6
34	IBM SAN Controller DS4800	1
35	IBM System P5 9133-55A	1
36	IBM Storage 450GB x 16	3
37	IBM Storage 146GBx16	2
38	IBM System Storage Controller DS5100	1
39	IBM 570 Server	8
40	Screen with Keyboard	1
41	IBM DAT Drive	1
42	Dell PowerEdge 146GBx2, 300 GBx4	1
43	Dell PowerEdge 146GBx4	1
44	HP ProLiant DL 180G5 1TBx6	1

Congratulations!!! On being an Environmentally & Socially Responsible Organization and abiding by the GOI, E-waste Rules.

You have taken the initiative, and we shall ensure that your E-Waste is treated and disposed in the most efficient manner with a Zero Emission Policy to conserve and protect our environment

E-Incarnation Recycling Private Limited assumes ownership, possession, title, responsibility and control over the received materials.

**Thanking You,
For, E-Incarnation Recycling Pvt. Ltd.**


Authorized Signatory



Company Seal

CERTIFICATE

OF RESPONSIBLE RECYCLING

ISSUED TO

WOCKHARDT LIMITED.

This document certifies that E-Incarnation Recycling Private Limited, processes, recycles, destroys and displaces the received material in an environmentally sustainable manner that is in accordance with all local, state and central Government regulations. Further E-Incarnation Recycling Private Limited certifies that all intellectual client data will be destroyed or erased properly from the hard drives and other media.

E-Incarnation Recycling Private Limited assumes ownership, possession, title, responsibility and control of the materials received on 19.03.2022; listed in Section A of this Certification.

Contact: WOCKHARDT TOWERS, BANDRA KURIA COMPLEX,
BANDRA EAST, MUMBAI - 400051.

Section A: Materials Received for processing

ERPL Customer Id: 585 Transaction Id: 1507

Materials Received

Quantity

AS PER LIST

-



Reg. No. MPCB/ROHQ/HSMD/Author./21/EW-23.

E-Incarnation Recycling Pvt. Ltd. Mardia House, 96, C. P. Tank Road, Mumbai - 400 004.

Tel - 022 66251300-33. Fax - 022 23877102. E-Mail - recycle@E-Incarnation.com. Web - www.E-Incarnation.com.



Receipt No. – 1507

Date – 19/03/2022

Received from – Wockhardt Limited.

Particulars –

Particulars	Qty
Laptop	354
Desktop	23
LCD	63
Printer	9
Server	12
Server Chassi	2
Thinclient	178
All in One PC	2
Bluecoat Proxy	2
Firewall	2
DLP	1
Keyboard	23
Toner	10
Solt Tab	367

Congratulations!!! On being an Environmentally & Socially Responsible Organization and abiding by the GOI, E-waste Rules.

You have taken the initiative, and we shall ensure that your E-Waste is treated and disposed in the most efficient manner with a Zero Emission Policy to conserve and protect our environment.

E-Incarnation Recycling Private Limited assumes ownership, possession, title, responsibility and control over the received materials.

Thanking You,
For, E-Incarnation Recycling Pvt. Ltd.



Packaging full producer verification form

Overview

Data Year 2023

Comply Direct membership number CD02/00485

NPWD code NPWD265833

Company details

Company name Wockhardt UK Ltd

Trading name (if different to above) Wockhardt UK Ltd

Company reg no 05835570

VAT number 879679725

Telephone 01978 661 261

Fax

Email Andrew.Kras@wockhardt.co.uk

Registered address line 1 Ash Road North

Registered address line 2 Wrexham Industrial Estate

Registered address line 3

Registered town Wrexham

Registered county Wrexham

Registered postcode LL13 9UF

Registered country Wales

Turnover

Turnover (in millions to 3 decimal places e.g. 12.751) 59.194

Business description and SIC code

SIC code 21.20

Registration type

Registration type Individual company

Registration subtype N/A

Primary contact

Title Mr

First name Andrew

Surname Kras

Job title Senior Purchasing Officer
Address line 1 Ash Road North
Address line 2 Wrexham Industrial Estate
Address line 3
Town Wrexham
County Wrexham
Postcode LL13 9UF
Country Wales
Telephone 07776655861
Mobile
Fax
Email Andrew.Kras@wockhardt.co.uk

Audit contact

Title Mr
First name Andrew
Surname Kras
Job title Senior Purchasing Officer
Address line 1 Ash Road North
Address line 2 Wrexham Industrial Estate
Address line 3
Town Wrexham
County Wrexham
Postcode LL13 9UF
Country Wales
Telephone 07776655861
Mobile
Fax
Email Andrew.Kras@wockhardt.co.uk

Table 1a: Summary of UK Packaging activity (in tonnes)

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Raw material manufacturing	0	0	0	0	0	0	0
Conversion	0	0	0	0	0	0	0
Packing/filling	138	0	0	0	11	54	0
Selling	138	0	0	0	11	54	0

Table 2a: UK sourced packaging exported by you (in tonnes)

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Raw material manufacturing	0	0	0	0	0	0	0
Conversion	0	0	0	0	0	0	0
Packing/filling	5	0	0	0	1	5	0
Selling	5	0	0	0	1	5	0

Table 2b: UK sourced packaging exported by a third party (in tonnes)

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Raw material manufacturing	0	0	0	0	0	0	0
Conversion	0	0	0	0	0	0	0
Packing/filling	0	0	0	0	0	0	0
Selling	0	0	0	0	0	0	0

Table 3a: Packaging imported (and remaining in the UK) for the purpose of the named activity (in tonnes)

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Conversion	0	0	0	0	0	0	0
Packing/filling	0	0	0	0	0	0	0
Selling	379	309	48	0	245	0	1

Table 3b: Imported packaging for which you are the end user (in tonnes)

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Transit packaging	14	0	0	0	8	0	0

Table 3c: Imported packaging which is subsequently exported (in tonnes)

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Imports exported	18	17	2	0	14	0	0

Main packaging activity

Main packaging activity Importing

Calculations methods

Supplier data Yes

Sales records Yes

Sample weighing Yes

Data prepared by a consultant Yes

Consultant name Comply Direct

Pareto analysis (eg. 80% of lines) Yes

Agreed protocols used No

Protocol details No protocol used

Statement of obligations

This section shows the level of obligation your company is responsible for. In particular, the minimum recycling target by material, total recovery obligation and total recycling obligation relate to the specific number of Packaging Recovery Notes that need to be purchased in order to ensure compliance.

	Paper	Glass	Aluminium	Steel	Plastic	Wood	Other
Obligated Tonnage by Material	324	161	25	0	144	42	1
Minimum Recycling Target by Material	269	132	17	0	88	15	N/A

Recycling obligation 536

Total materials recycling 521

Net recycling (total recycling minus total of materials recycling) 15

Total Recycling Obligation 536

Declaration

It is an offence to deliberately give false or misleading information and you may be liable for prosecution.

- I hereby declare that the information in this data form is true to the best of my knowledge and belief. I agree to inform Comply Direct of any changes to the information given in line with the Comply Direct standard terms and conditions of membership.
- I declare that the data submitted as appears in this form is calculated in such a way that it meets the regulatory requirement of being as accurate as reasonably possible.
- I declare that I have read the terms and conditions of membership as made available on the Comply Direct website and I agree to abide by the rules laid down by them.
- I declare that I am an authorised representative for the company.

This form must be signed and dated by a Legal Director (as listed on Companies House), Company Secretary or partner.

Print name of appropriate person:

Signature of appropriate person:

Date:

Job title of appropriate person:

Please return this form by uploading into the member's area of our website, or by email, fax or post to the below and please keep a copy for your own records.

Comply Direct Limited
The Old Saw Mill, Broughton Hall, Skipton, North Yorkshire BD23 3AE
W: www.complydirect.com T: 0844 873 1034 F: 0844 873 1035 E: info@complydirect.com



WASTE DISPOSAL

1 **INTRODUCTION**

This procedure does not cover effluent discharges.

Waste materials can arise from a number of sources. In all cases it is important that they are correctly segregated and fully identified.

References:

- (1) The Collection and Disposal of Waste Regulations 1998
- (2) The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
- (3) The (Classification, Packaging and labelling) Regulations 2009
- (4) The Misuse of Drugs Regulations 2001
- (5) The Genetically Modified Organisms (Contained Use) Regulations 2014
- (6) The Hazardous Waste (England and Wales) Regulations 2005.
- (7) Welsh Recycling Legislation 2024

2 LIST OF WASTES

2.1 The routine waste streams are listed below, abnormal or unusual circumstances may need to be assessed using WM3 and service provider advice as guidance.

TYPE OF WASTE STREAM	HANDLED ON SITE		SEGREGATION	CONTAINER	METHOD OF DISPOSAL
GENERAL	Disposal through the normal site skips.			Blue/green and black bin	
LABORATORY/ PRODUCTION /ENGINEERING PRODUCTS	NON HAZARDOUS medicinal products that can be disposed of under waste code 18 01 09 Where safe to do so outer packaging should be removed for recycling	CONTROLLED DRUGS Specific control over the witnessed destruction of Controlled drugs	YES	Red bin bags/yellow griff bins	Incineration
		GENETICALLY MODIFIED ORGANISM Specific controls over the deactivation	YES	Red bin bags/yellow griff bins	Incineration
		OTHER Other medicinal products	NO	Red bin bags/yellow griff bins	Incineration
	HAZARDOUS medicinal products that should be disposed of under waste code 18 01 08 Products to be disposed of in their packaging	CONTROLLED DRUGS Specific control over the witnessed destruction of Controlled drugs	YES	Red bin bags/yellow griff bins	Incineration
		GENETICALLY MODIFIED ORGANISM Specific controls over the deactivation	YES	Red bin bags/yellow griff bins	Incineration
		OTHER Other medicinal products	YES	Red bin bags/yellow griff bins	Incineration

TYPE OF WASTE STREAM	HANDLED ON SITE	SEGREGATION	CONTAINER	METHOD OF DISPOSAL
LABORATORY/ PRODUCTION /ENGINEERING CHEMICALS	NON HAZARDOUS chemicals to be assessed based on their hazard properties	YES	Appropriate for type, disposed of within container	Incineration
	HAZARDOUS chemicals to be assessed based on their hazard properties Specifically segregated based on their hazardous properties e.g. chlorinated solvents	YES	Appropriate for type, disposed of within original container Solvents drum of an appropriate size	Incineration
LABORATORY/ PRODUCTION /ENGINEERING OTHER	NON HAZARDOUS Paper/Cardboard/Packaging materials/glass None product contaminated consumables Empty containers that can be confirmed as not contaminated	NO	Griff bins Cardboard skip	Recycling
	NON HAZARDOUS Sensitive printed matter will be segregated and shredded	YES	Specific skip or bin	
	HAZARDOUS Clinical and infections wastes	YES	Sharps bins Yellow or Orange bin bags/Griff bins Including tag Dedicated bin	Incineration or appropriate method
	HAZARDOUS Contaminated materials will be treated the same as the contaminating product or chemical	YES	Red bin bags Griff Bins	
	HAZARDOUS Oils/lubricants/Greases/Fuels	YES	Appropriate to item	
	HAZARDOUS Aerosols	YES	205 litres drum or dolav	

TYPE OF WASTE STREAM	HANDLED ON SITE	SEGREGATION	CONTAINER	METHOD OF DISPOSAL
	HAZARDOUS Batteries are segregated and disposed of	YES	Specified UN box	
WASTE ELECTRICAL	Electrical items will be assessed and disposed off	YES	As required	Appropriate method
METAL	Metal items will be assessed and disposed off	YES	Skip or small griff bin	Recycling
Office recycling	Food Paper and Cardboard Metal, Plastic and Carton	YES	Bins	Recycling

3 **IDENTIFICATION FOR HAZARDOUS and NON-HAZARDOUS WASTE**

- 3.1 Segregation must follow that outlined in sections 2 on separate waste summary **forms** medicinal product or chemical clearly listing each item, concentration, quantity involved and type /size of container. (Size by volume /weight is the most useful expression for this need).

Note: Concentration expressed as % of the active / hazardous contents in the product / material. Quantity should be total for disposal including packing i.e. vials, ampoules, finished packs.

Product / actives / chemicals should be a full description including such items as strength, vial, ampoule, pack, etc. where applicable.

- 3.2 All types of waste listed separately by following the above segregation must be placed in separate containers based on their hazardous properties. Incompatible materials e.g. acids/bases and oxidisers must be separated. Materials considered dangerous for transport must be separated.
- 3.3 All waste containers must be clearly identifiable with the waste type contained within.
- 3.4 If the waste is collated by the stores department, each box, drum or container must be identified and a waste summary form must be attached which identifies the contents. A second copy of the form should be added to allow processing. Specific information relating to the waste code and GMO will be required. No other labels or information must be attached or readable.

4 **PACKAGING AND LABELLING**

Refer to ENV/003 for information concerning UN containers and their identification. The waste disposal contractor supplies labels for transport with the necessary identification and hazard labelling.

- 4.1 All waste will need to be segregated for transport needs.

- 4.2 Controlled Drugs

Refer to WDOP/055 for the handling of any type of controlled substance waste.

A list of CD's and Schedules can be found in WDOP/055.

Off-site witnessed destruction is required for the following: -

Schedule 2	All semi-finished product, finished product & raw material.
Schedule 3	All semi-finished product, finished product & raw material.
Schedule 4 Pt 1	All semi-finished product, finished product & raw material.
Schedule 4 Pt 2	All semi-finished product, finished product & raw material.

Use Form 1102.

Off-site witnessed destruction is not required for the following :-

Schedule 5	All semi-finished product, finished product & raw material.
------------	---

Use Form 3728.

Waste CDs from production, QC, Micro and Development must be returned to the CD room in a Griff bin together with a completed form 1102.

The Authorised Key Holder will receive the waste, check and sign form 1102.

Each department should be responsible for their own internal waste record.

Controlled CD waste must not be stored outside the CD room.

The company's Authorised Person and Authorised Key Holders will be responsible for the off-site disposal of CD waste. Details of this procedure can be found in WDOP/055.

5 DISPOSAL

5.1 Hazardous, Non-Hazardous and Controlled Drug Waste

5.1.1 After completion of identification and packaging pass completed waste and waste forms to stores, use form 1102 for CD waste (except Schedule 5) and forms 3727 (chemicals) and 3728 (medicinal products) and for all other waste * ensure that the form has been signed.

*Exception are Microbiological waste and waste from the surgery which is contained separately and not sent to the stores.

Form 1102 should be checked and signed by a second person unless the form has been completed by an Authorised Key Holder who is permitted to countersign the form.

5.1.2 Stores will collate the griff bins into larger containers or pallets.

5.1.3 Stores will assess the form details, confirm segregation and allocate to a suitable pallet where necessary.

Incorrect pallets, containers or paperwork will result in material being returned to department concerned.

5.1.4 Stores will assemble and store pallets as instructed by the waste summary form.

On completion of a pallet, it will be overwrapped and the pallet number clearly displayed and the form completed and transportation labelled applied.

Movement of goods off site requires completion of a Consignment Note for the Carriage and Disposal of Waste.

In this case the company operating the removal will often arrange the documents.

5.1.5 In certain circumstances it may be necessary to have waste sorted by a specialist external chemist. This will be coordinated by the waste provider and the department producing the waste. Sorting will take place in the reject area under supervision. PPE must be considered.

5.1.6 In all cases it is the waste producers responsibility, (i.e. CP) for correct procedures and safe disposal.

5.2 General Waste

5.2.1 Movement of goods off site requires the completion of waste transfer note. This can cover a period rather than a single load.

6 WASTE NOTIFICATION

All waste disposal sites are licensed. These sites and the movement of goods are subject to strict procedures.

6.1 Consignment Notes (for Hazardous and Controlled Drug Waste)

6.1.1 Consignment notes can be completed electronically. Documentation is sent to Wockhardt via the waste portal.

6.1.2 If paper the set consists of 4 copies with completion and distribution as follows:

- White – Producer (CP/Wockhardt)
- Pink – Carrier
- Yellow – Consignee
- Blue - Records

6.1.3 Each delivery must have its own set of notes. Each copy must be accompanied by the necessary set of relevant Waste forms (3727/3728 or 1102). All Waste forms must have a page number and the consignment note number for the load.

6.1.4 Sections A and B are completed prior to collection.

6.1.5 When the delivery is collected the carrier must complete Section C and the Producer (CP) Section D.

6.1.6 Where paper based, three copies to be given to the driver in an envelope.

6.1.7 The final copy or returned copy is a file copy, which must be retained by CP for at least 5 years.

6.1.8 Consignee returns will be received for hazardous waste shipments.

6.1.9 The site holds a Hazardous Waste Registration renewed annually by the EHS department.

7 WASTE CONTAINERS

7.1 Empty containers and labels required for this process are maintained on stock and are requested by the department.

8 COLLECTION

8.1 All collection vehicles must report to the gatehouse for instruction from the person with authority to allow the movement of the waste concerned.

Waste chemicals/product	-	Stores
Clinical waste	-	Microbiological supervision
Other waste	-	Stores
Recycle Skip	-	Stores/Dispatch

Waste can arise from many sources. The above is not a definitive list of sources / types or methods of disposal. If any waste does not fit the above contact the EHS department for advice. Waste produced by contractors will be their responsibility.

9 FORMS

Form 3727	Waste Chemical Record
Form 3728	Waste Medicinal Product Record
Form 1102	Departmental CD Waste Record Form

10 REFERENCES

ENV/003	Packaging of Hazardous Waste
WDOP/055	Controlled Drugs – Safe Custody, Movement and Access

11 APPENDICES

Appendix 1	Hazardous Properties
------------	----------------------

Hazardous Properties	
Appendix I	Page 1 of 1

- H1 Explosive substances and preparations, which may explode under the effect of flame or which, are more sensitive to shocks or friction than dinitrobenzene.
- H2 Oxidizing substances and preparations which exhibit highly exothermic reactions when in contact with other substances, particularly flammable substances.
- H3-A Highly flammable
 Liquid substances and preparations having a flash point below 21C (including extremely flammable liquids), or
 Substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or
 Solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or
 Gaseous substances and preparations which are flammable in air at normal pressure, or
 Substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities.
- H3-B Flammable liquid substances and preparations having a flash point equal to or greater than 21C and less than or equal to 55C.
- H4 Irritant non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, can cause inflammation.
- H5 Harmful substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may involve limited health risks.
- H6 Toxic substances and preparations (including very toxic substances and preparations) which, if they are inhaled or ingested or if they penetrate the skin, may involve serious, acute or chronic health risks and even death.
- H7 Carcinogenic substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.
- H8 Corrosive substances and preparations which may destroy living tissue on contact.
- H9 Infectious substances containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms.
- H10 Teratogenic substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce non-hereditary congenital malformations or increase their incidence
- H11 Mutagenic substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce hereditary genetic defects or increase their incidence.
- H12 Substances and preparations which release toxic or very toxic gasses in contact with water, air or an acid.
- H13 Substances and preparations capable by any means, after disposal, of yielding another substance, e.g. a leachate which posses any of the characteristics listed above.
- H14 Ecotoxic substances and preparations which present or may present immediate or delayed risks for one or more sectors of the environment.

WASTE DISPOSAL	
Amendment History	Page 1 of 1

Version No. and Effective Date	Amendment History
1.0 06/05/11	Put document into Doc Compliance format Form F1 changed Manager sign off to responsible person to meet current working regime
2.0 16/11/12	Included form F2 'Departmental CD waste record form'. Included sections 8 and 9. Reference to controlled drugs consolidated into a separate section (2.4).
3.0 08/01/16	3 year review. All forms removed and association added to forms 1101 and 1102. Included reference to WDOP/055 in section 9.
4.0 14/08/17	Additional completion notes added to Section 5.1.1 for Form 1102. Minor text changes to Section 6.1.2. "Relevant" added and brackets moved.
5.0	Section 2.4 update to place CD waste in a Griff bin prior to taking to CD room. The Authorised Key Holder will receive the waste, check and sign form 1102. Refer to CAPA 5265.
6.0	Update to add GMO waste streams
7.0	Amendment to the waste code used for GMO waste streams
8.0	Removal of Special waste update to the list of wasters and update to notification process section 6.
9.0	Documents can be retrieved electronically and paper based consignment notes may not be required. Amendment to solvent and aerosol containers. Griff bins can be collated into larger containers or placed on pallets. Addition of office recycling Amendments to all sections containing information about forms. Addition of receptacles for chemicals. Addition of labelling for transport. Addition of the use of external chemist support for sorting Section 5.1.5 Section 3.2 improved to define segregation of wastes and to consider materials dangerous for transport. Addition of palletised waste.

Certificate



To whomsoever it may concern

Certificate No : 4100015870

This is to certify that

WOCKHARDT LIMITED (BIOTECH PARK)

H-14-2, MIDC AREA,
 GANGAPUR ROAD, WALUJ, AURANGABAD, MAHARASHTRA
 CHHA. SAMBHAJI NAGAR

Maharashtra

is a valid member of

**GREEN GENE ENVIRO PROTECTION AND INFRASTRUCTURE
 LIMITED**

for Alternate Fuel Resource Facility.

This membership is valid for a period of
5 Years

For, **GREEN GENE ENVIRO PROTECTION AND
 INFRASTRUCTURE LIMITED**

Date of issue : 29.07.2026

Date of expiration : 28.07.2031

Place of issue : SURAT



Director/Authorised signatory

Waste Information

SrNo	Type Of Waste	Sign Qty(TPA)	SrNo	Type Of Waste	Sign Qty(TPA)
1	ANY PROCESS OR DISTILLATION RESIDUE - 36.1	10.000	2	CHEMICAL SLUDGE FROM WASTE WATER TREATME - 35.3	10.000
3	DATE. - 28.5	10.000		-	0.000
Total Sign Qty (TPA)					30.000

Unit Location

Plot No. B-18,
 Shalgaon Bombalewadi Industrial Area,
 Sangli, Sangli, Maharashtra, 415304
 Phone : +91 63521 13258
 Email : karad@luthraindia.com

Corporate Office

COE Building, Gujarat Eco Textile Park,
 Block No. 181/B, Village Baleshwar,
 Taluka Palsana, Surat - 394315
 Phone : +91 70690 84907
 Website : www.luthraindia.com

Registered Office

Unit 1817, 18th Floor, Lodha Codename No. 1,
 One Lodha Place, Senapati Bapat Marg,
 Upper Worli, Lower Parel, Delisle Road, Mumbai,
 Mumbai-400013, Maharashtra

Recycling Solution Pvt Ltd.(Lessee), Gepil
(Leaser\owner) -- [13376]
(Hazardous Waste Manifest)

Manifest No: 3058373
Manifest Date: 23/09/2025

Copy 6

To be returned by the operator of the facility to the occupier after treatment and disposal of hazardous material/waste.

Sender's Details					
Sender Name	Wockhardt Limited - [15879]				
Address	138, GIDC Estate, GIDC City : 138, GIDC Estate Taluka : ANK Distict: ANK Pin no: 393002				
Contact Details	9428326378, RSura@wockhardt.com	GPS Coordinates	Lat: , Long:		
Guardian Detail	Rohit H Sura, Sr.Executive, 9428326378, rsura@wockhardt.com				
Receiver's Details					
State	Gujarat	Type of Facility	Pre- processing		
Facility Details	Recycling Solution Pvt Ltd.(Lessee), Gepil (Leaser\owner) - [13376]		Intremediat Facility		
Contact Details	7069028761, pankaj.sinha@RS-PL.com	GPS Coordinates	Lat: 21.569852283399893, Long: 72.99642562866211		
Address	223 ,GIDC, Estate City : Panoli, Taluka : ANK Distict: ANK Pin no: 394116				
Waste Details					
Waste Details	I~28~28.1~Process Residue and wastes~~				
Waste Intended for	PPRO	Total Qty	6.010MT	Consistency	semi solid
Transporter Details					
Name	RSPL	Contact Details	7069028650 prashant.bansari@rs-pl.com		
Address	PLOT 223 GIDC ESTATE PANOLI ANKLESHWAR GIDC PANOLI ANKLESHWAR				
Vehicle Details					
Vehicle no	GJ16AU9752(IMEI No:869310060632117)			GPS Enabled	Yes
Driver name	SHAMBHUNATH	Driver Contact No	7874277257	Type of Vehicle	Truck
Waste Transportation Details					
Vehicle Depart.		Number of Drums	27	Loose Waste	6.010
Remarks	Process Residue			No of bags	0
Sender's Declaration: (1) The above contents of hazardous/ other wastes consignment are fully and accurately described above by proper shipping name and are categorized, packed, marked and labeled, and are in all respects in proper conditions for its transport from aforementioned location to common facility or captive facility or actual user by way of road/ transportation in accordance with the applicable central as well as state government regulations. (2) I have obtained membership of common facilities/ carried out agreement with actual user for disposal/ actual use of hazardous waste having authorization under Rule-9. (3) I do hereby verify that no part of manifest is false and nothing has been concealed. If any information sprouts to be false or concealed, I will be held responsible for the consequences under HOWM Rules, 2016 and amendments thereof.					
Name and stamp of sender: WOCKHARDT LIMITED (BULK DRUG DIVISION) PLOT NO. 138, G.I.D.C. ESTATE, ANKLESHWAR - 393002. PH. : 02646 - 661444 FAX : 02646 - 661556		Date: <u>23.09.2025</u>		Signature: <u>Bud...</u>	
Transporter's Acknowledgement of Receipt of Waste Stamp: _____ Date: <u>23.09.2025</u> Signature: <u>Shambh...</u>					
Receiver's Certification of Receipt of Hazardous Waste I, hereby declare that the said waste is received at the facility/unit for which I have valid CCA (under Rule-9 in case of recycling disposal/ utilization. I also declare this information to be true failing which I will be held responsible for the consequences under HOWM Rules, 2016 and amendments thereof. I hereby, accept/ reject the manifest.					
Stamp: _____		Date: <u>23/9/25</u>		Signature: <u>...</u>	

APPENDIX 7: Quality Assurance Certificates (GMP)

(Biotech API Certificates)



MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

Certificate of Good Manufacturing Practices for Raw Materials ACTIVE PHARMACEUTICALS

LINE OF ACTIVE BIOLOGICAL PHARMACEUTICAL INGREDIENTS

The Brazilian National Health Surveillance Agency - ANVISA, through Resolution RE No. **991**, of **March 13, 2026**, published in the Official Gazette of the Union (DOU) on **March 16, 2026**, certifies that the company below is periodically inspected and monitored by the National Health Surveillance System and that it complies with the Good Manufacturing Practices guidelines given by Brazilian legislation, which is in line with the recommendations of the World Health Organization.

Manufacturer: Wockhardt Limited

Address: Biotech Park, H-14/2A, MIDC Waluj, Chhtrapati Sambhajnagar 431136, Maharashtra State

Country: India Unique code: A.000631

Applicant: Farma Vision Importação e Exportação De Medicamentos Ltda.

CNPJ: 09.058.502/0001-48 File(s):

1455540/24-2 Certificate of Good

Manufacturing Practices for Active Pharmaceutical Ingredients: Biological active pharmaceutical ingredients: insulin glargine.

This certification is valid until **March 16, 2028**, and may be cancelled if the competent health authority verifies non-compliance with the requirements stipulated by current Good Manufacturing Practices standards.



This document was electronically signed by **Renata de Lima Soares, General Manager of Sanitary Inspection and Enforcement**, on March 18, 2026, at 3:27 PM, Brasília time, pursuant to § 3 of Article 4 of Decree No. 10,543, of November 13, 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.



The authenticity of this document can be verified on the website <https://sei.anvisa.gov.br/autenticidade>, providing the verification code **4142680** and the CRC code **620245EF**.

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 8913 Insp GMP 8913/12228-0008[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

Part 1

Issued following an inspection in accordance with :

Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : WOCKHARDT LIMITED

Site address : WOCKHARDT LIMITED, 87/A SILVER INDUSTRIAL ESTATE, BHIMPORE, NANI DAMAN, DAMAN, IN-396210, INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 16 of The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 17/12/2018, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

-
- (1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.
 - (2) These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.13] Tablets

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

29/03/2019 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

Medicines and Healthcare products Regulatory Agency

Tel : Confidential

U.T. ADMINISTRATION OF DNH, DAMAN & DIU
DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE
MOTI DAMAN-396220

No. DCD/D&D/LA/2021-2022/1599

Dated: 15/01/2022

LICENCE VALIDITY CERTIFICATE
(See rule 72 and 84 C)

Ref: No. Nil dated 23/12/2021.

- 1) A Licence No. DD/61 & DD/62 granted on 18/10/1994 to M/S. WOCKHARDT LIMITED., situated at 87-A, Silver Industrial Estate, Bhimpore, Daman -396 210, INDIA, in Form 25 and Form 28 shall remain perpetually Valid upto 31/12/2026 as the licensee has deposited a licence retention fee vide Challan No. 001642 dated 22/12/2021 as per the Drugs & Cosmetics Rules, 1945.
- 2) Names of drugs: As per list attached.
- 3) Names of approved competent technical staff: As per list attached.
- 4) Firm shall comply to the Drugs & Cosmetics Act, 1940 & Rules 1945 thereunder.

Dated:

15 FEB 2022



(Dr. V. K. DAS)

Director,
Medical & Health Services,
Drugs Licensing Authority
UT of DNH, Daman & Diu
Daman.

NOTE:

- 1) In Form 25 for paragraph 3, the following paragraph shall respectively be substituted, 3. "The Licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs & Cosmetics Act, 1940 (23 of 1940) and Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach".
- 2) In Form 28 for paragraph 4, the following paragraph shall respectively be substituted, "The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs & Cosmetics Act, 1940n (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach".

ЕВРАЗИЙСКИЙ ЭКОНОМИЧЕСКИЙ СОЮЗ

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ

СЕРТИФИКАТ

СООТВЕТСТВИЯ ПРОИЗВОДСТВА ЛЕКАРСТВЕННЫХ СРЕДСТВ ТРЕБОВАНИЯМ ПРАВИЛ
НАДЛЕЖАЩЕЙ ПРОИЗВОДСТВЕННОЙ ПРАКТИКИ ЕВРАЗИЙСКОГО ЭКОНОМИЧЕСКОГО СОЮЗА

№ GMP/EAEU/RU/00925-2023

Срок действия с 07.07.2023 по 06.07.2026

Выдан по итогам проведения фармацевтической инспекции в соответствии с Правилами проведения фармацевтических инспекций, утвержденными Решением Совета Евразийской экономической комиссии от 3 ноября 2016 г. № 83

Министерство промышленности и торговли Российской Федерации
(Минпромторг России)

(полное и сокращенное наименования уполномоченного органа)

подтверждает следующее:

проведена фармацевтическая инспекция

Вокхард Лимитед

(полное наименование производителя)

Участок № 87-А, Сильвер Индастриал Эстейт, Бхимпор, Нани Даман 396 210.
Индия

(адрес производственной площадки)

на основании заявления о выдаче сертификата соответствия производителя (производителя нерезидента) лекарственных средств для медицинского применения требованиям Правил надлежащей производственной практики Евразийского экономического союза от 29.11.2022 № 299.

На основании сведений, полученных при проведении инспектирования, последнее из которых было проведено 03.07.2023 - 07.07.2023, установлено, что данное фармацевтическое производство соответствует требованиям Правил

GMP/EAEU/RU/00925-2023

надлежащей производственной практики Евразийского экономического союза, эквивалентных Принципам и Руководству Европейского союза по надлежащей производственной практике лекарственных средств для медицинского и ветеринарного применения и принципам Системы сотрудничества фармацевтических инспекций (PIC/S).

Настоящий сертификат отражает статус производственной площадки на момент проведения фармацевтической инспекции и по истечении более 3 лет от даты последнего дня последнего инспектирования не может считаться документом, свидетельствующим о статусе соответствия. Срок действия сертификата может быть сокращен при использовании соответствующих принципов управления рисками при наличии соответствующей записи в поле «Ограничения или пояснительные заметки, касающиеся области применения настоящего сертификата».

Сертификат является действительным в случае представления всех его листов (как основных листов, так и дополнительных листов).

Аутентичность (подлинность) настоящего сертификата можно проверить в базе данных Минпромторга России.

Если сертификат не представлен в указанной базе данных, следует обратиться в уполномоченный орган, его выдавший.

Заместитель Министра



06 сентября 2023 г.

(дата выдачи сертификата)

Е.Г. Приезжева

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ
GMP/EAEU/RU/00925-2023

☒ Лекарственные средства для медицинского применения

☐ Лекарственные препараты для клинических исследований (испытаний)

Код

Наименование

I. ПРОИЗВОДСТВЕННЫЕ ОПЕРАЦИИ – ЛЕКАРСТВЕННАЯ ПРОДУКЦИЯ

1.1 Стерильная продукция

1.1.1 Производимая в асептических условиях (операции обработки для следующих лекарственных форм):

1.1.1.1. Жидкие лекарственные формы большого объема

1.1.1.2. Жидкие лекарственные формы малого объема

1.1.1.3. Лиофилизаты

1.1.1.4. Твердые лекарственные формы и имплантаты

1.1.1.5. Мягкие лекарственные формы

1.1.1.6. Прочая продукция, производимая в асептических условиях

1.1.2. Подвергаемая финишной стерилизации (операции обработки для следующих лекарственных форм):

1.1.2.1. Жидкие лекарственные формы большого объема

1.1.2.2. Жидкие лекарственные формы малого объема

1.1.2.3. Твердые лекарственные формы и имплантаты

1.1.2.4. Мягкие лекарственные формы

1.1.2.5. Прочая продукция, подвергаемая финишной стерилизации

1.1.3. Выпускающий контроль качества (выпуск серии)

1.2 Нестерильная продукция

☒ 1.2.1. Нестерильная продукция (технологические операции для получения следующих лекарственных форм):

1.2.1.1. Капсулы в твердой оболочке

1.2.1.2. Капсулы в мягкой оболочке

1.2.1.3. Жевательные лекарственные формы

1.2.1.4. Импрегнированные лекарственные формы

1.2.1.5. Жидкие лекарственные формы для наружного применения

1.2.1.6. Жидкие лекарственные формы для внутреннего применения

1.2.1.7. Медицинские газы

1.2.1.8. Прочие твердые лекарственные формы

1.2.1.9. Препараты, находящиеся под давлением

1.2.1.10. Радионуклидные генераторы

1.2.1.11. Мягкие лекарственные формы

1.2.1.12. Свечи (суппозитории)

☒ 1.2.1.13. Таблетки: таблетки

1.2.1.14. Трансдермальные пластыри

GMP/EAEU/RU/00925-2023

	1.2.1.15. Прочая нестерильная продукция
☒	1.2.2. Выпускающий контроль качества (сертификация серии)
1.3	Биологическая лекарственная продукция
	1.3.1. Биологическая лекарственная продукция:
	1.3.1.1. Продукты крови
	1.3.1.2. Иммунобиологическая продукция
	1.3.1.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	1.3.1.4. Генотерапевтическая продукция
	1.3.1.5. Биотехнологическая продукция
	1.3.1.6. Продукция, выделенная из животных источников или органов (тканей) человека
	1.3.1.7. Тканеинженерная продукция (продукция тканевой инженерии)
	1.3.1.8. Прочая биологическая лекарственная продукция
	1.3.2. Выпускающий контроль (сертификация серии) (перечень видов продукции):
	1.3.2.1. Продукты крови
	1.3.2.2. Иммунобиологическая продукция
	1.3.2.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	1.3.2.4. Генотерапевтическая продукция
	1.3.2.5. Биотехнологическая продукция
	1.3.2.6. Продукция, выделенная из животных источников или органов (тканей) человека
	1.3.2.7. Тканеинженерная продукция (продукция тканевой инженерии)
	1.3.2.8. Прочая биологическая лекарственная продукция
1.4	Прочая лекарственная продукция или производственная деятельность
☒	1.4.1. Производство:
	1.4.1.1. Растительная продукция
	1.4.1.2. Гомеопатическая продукция
☒	1.4.1.3. Прочая продукция: прочие группы лекарственных препаратов: таблетки



Заместитель Министра

06 сентября 2023 г.

(дата выдачи сертификата)

Е.Г. Приезжева

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ
GMP/EAEU/RU/00925-2023

	1.4.2. Стерилизация фармацевтических субстанций, вспомогательных веществ, готовой продукции:
	1.4.2.1. Фильтрация
	1.4.2.2. Сухожаровая стерилизация
	1.4.2.3. Стерилизация паром
	1.4.2.4. Химическая стерилизация
	1.4.2.5. Стерилизация гамма-излучением
	1.4.2.6. Стерилизация электронным излучением
	1.4.3. Прочее
1.5	Упаковка
☒	1.5.1. Первичная упаковка:
	1.5.1.1. Капсулы в твердой оболочке
	1.5.1.2. Капсулы в мягкой оболочке
	1.5.1.3. Жевательные лекарственные формы
	1.5.1.4. Импрегнированные лекарственные формы
	1.5.1.5. Жидкие лекарственные формы для наружного применения
	1.5.1.6. Жидкие лекарственные формы для внутреннего применения
	1.5.1.7. Медицинские газы
	1.5.1.8. Прочие твердые лекарственные формы
	1.5.1.9. Препараты, находящиеся под давлением
	1.5.1.10. Радионуклидные генераторы
	1.5.1.11. Мягкие лекарственные формы
	1.5.1.12. Свечи (суппозитории)
☒	1.5.1.13. Таблетки: таблетки
	1.5.1.14. Трансдермальные пластыри
	1.5.1.15. Прочая нестерильная лекарственная продукция
☒	1.5.2. Вторичная упаковка
1.6	Контроль качества
	1.6.1. Микробиологические испытания: стерильность
☒	1.6.2. Микробиологические испытания: микробиологическая чистота
☒	1.6.3. Химические (физические) испытания
	1.6.4. Биологические испытания
2. ИМПОРТ ЛЕКАРСТВЕННОЙ ПРОДУКЦИИ	
2.1	Контроль качества импортируемой лекарственной продукции
	2.1.1. Микробиологические испытания: стерильность
	2.1.2. Микробиологические испытания: микробиологическая чистота
	2.1.3. Химические (физические) испытания
	2.1.4. Биологические испытания
2.2	Сертификация серии импортируемой лекарственной продукции

GMP/EAEU/RU/00925-2023

	2.2.1 Стерильная продукция:
	2.2.1.1. Производимая в асептических условиях
	2.2.1.2. Подвергаемая финишной стерилизации
	2.2.2. Нестерильная продукция
	2.2.3. Биологическая лекарственная продукция:
	2.2.3.1. Продукты крови
	2.2.3.2. Иммунобиологическая продукция
	2.2.3.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	2.2.3.4. Генотерапевтическая продукция
	2.2.3.5. Биотехнологическая продукция
	2.2.3.6. Продукция, выделенная из животных источников или органов (тканей) человека
	2.2.3.7. Тканеинженерная продукция (продукция тканевой инженерии)
	2.2.3.8. Прочая биологическая лекарственная продукция
2.3	Прочая деятельность по импорту (ввозу)
	2.3.1. Площадка физического импорта (ввоза)
	2.3.2. Импорт промежуточной продукции, подвергающейся дальнейшей обработке
	2.3.3. Прочее
3. ПРОИЗВОДСТВЕННЫЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ СУБСТАНЦИИ	
Фармацевтическая субстанция (субстанции):	
3.1	Производство фармацевтических субстанций методом химического синтеза
	3.1.1. Производство промежуточных продуктов фармацевтической субстанции
	3.1.2. Производство неочищенной фармацевтической субстанции
	3.1.3. Солеобразование (очистка): указать (например: перекристаллизация)
	3.1.4. Прочее

Заместитель Министра



06 сентября 2023 г.

(дата выдачи сертификата)

Е.Г. Приезжева

Страница 6 из 8

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ
GMP/EAEU/RU/00925-2023

3.2	Производство фармацевтических субстанций методами выделения из природных источников
	3.2.1. Выделение фармацевтических субстанций из источников растительного происхождения
	3.2.2. Выделение фармацевтических субстанций из источников животного происхождения
	3.2.3. Выделение фармацевтических субстанций из органов (тканей) человека
	3.2.4. Выделение фармацевтических субстанций из источников минерального происхождения
	3.2.5. Модификация выделенной фармацевтической субстанции
	3.2.6. Очистка выделенной фармацевтической субстанции
	3.2.7. Прочее
3.3	Производство фармацевтических субстанций с использованием биологических процессов
	3.3.1. Ферментация
	3.3.2. Производство с использованием клеточных культур
	3.3.3. Выделение (очистка)
	3.3.4. Модификация
	3.3.5. Прочее
3.4	Производство стерильных фармацевтических субстанций
	3.4.1. Фармацевтические субстанции, производимые в асептических условиях
	3.4.2. Фармацевтические субстанции, подвергаемые финишной стерилизации
3.5	Завершающие стадии производства фармацевтических субстанций
	3.5.1. Стадии физической обработки
	3.5.2. Первичная упаковка
	3.5.3. Вторичная упаковка
	3.5.4. Прочее
3.6	Контроль качества
	3.6.1. Физические (химические) испытания
	3.6.2. Микробиологические испытания (включая испытание на стерильность)
	3.6.3. Микробиологические испытания (исключая испытание на стерильность)
	3.6.4. Биологические испытания

GMP/EAEU/RU/00925-2023

**4. ПРОЧИЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ
СУБСТАНЦИИ**

Ограничения или пояснительные заметки, касающиеся области применения сертификата: -

Заместитель Министра



06 сентября 2023 г.

(дата выдачи сертификата)

Е.Г. Приезжева

Страница 8 из 8

EURASIAN ECONOMIC UNION
MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION

CERTIFICATE

OF CONFORMITY OF MANUFACTURING OF MEDICINAL PRODUCTS TO THE
REQUIREMENTS OF THE GOOD MANUFACTURING PRACTICE REGULATIONS OF
THE EURASIAN ECONOMIC UNION

No. GMP/EAEU/RU/00925-2023
Effective from 07.07.2023 to 06.07.2026

Issued according to results of performance of a pharmaceutical inspection in accordance with the Regulation for Performing Pharmaceutical Inspections approved with Resolution of the Council of the Eurasian Economic Commission No.83 of November 3, 2016

Ministry of Industry and Commerce of the Russian Federation
(Minpromtorg of Russia)

(full and abbreviated name of the authorized body)

hereby confirms the following:

the pharmaceutical inspection of the following entity has been performed:

Wockhardt Limited

(full name of the manufacturer)

Plot No.87-A, Silver Industrial Estate, Bhimpore, Nani Daman 396 210, India

(address of the manufacturing site)

on the basis of application for issuance of a certificate of conformity of the manufacturer (non-resident manufacturer) of medicinal products for medical use to the requirements of the Good Manufacturing Practice Regulations of the Eurasian Economic Union No.299 of November 29, 2022.

Based on the information obtained during the inspections, the last of which was performed from 03.07.2023 to 07.07.2023, it was established that this pharmaceutical manufacturing site complies with the requirements of the Good Manufacturing Practice Regulations of the Eurasian Economic Union, equivalent to the Principles and Guidelines of the European Union on Good Manufacturing Practice on medicinal products for medical and veterinary use and the principles of the Pharmaceutical Inspection Cooperation System (PIC/S).

000001007

GMP/EAEU/RU/00925-2023

This certificate shall display the status of the manufacturing site as of the time of the pharmaceutical inspection and, more than 3 years after the date of the last day of the last inspection, it can no longer be considered a document indicating the status of conformity. The effective term of the certificate may be reduced by applying appropriate risk management principles if an appropriate entry is made in the "Limitations or explanatory notes regarding the scope of this certificate" field. The certificate shall be deemed valid if all its sheets (both main sheets and additional sheets) are presented.

The authenticity of this certificate can be checked in the database of the Ministry of Industry and Trade of Russia.

If the certificate is not presented in the specified database, the authorized body that has issued it should be contacted.

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**
GMP/EAEU/RU/00925-2023

X	Medicinal products for medical use
☐	Medicinal products for clinical studies (trials)
Code	Name
I. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS	
1.1	Sterile products
	1.1.1. Manufactured under aseptic conditions (processing operations for the following dosage forms):
	1.1.1.1. Large volume liquid dosage forms
	1.1.1.2. Small volume liquid dosage forms
	1.1.1.3. Lyophilisates
	1.1.1.4. Solid dosage forms and implants
	1.1.1.5. Soft dosage forms
	1.1.1.6. Other products manufactured under aseptic conditions
	1.1.2. Products subject to terminal sterilization (processing operations for the following dosage forms):
	1.1.2.1. Large volume liquid dosage forms
	1.1.2.2. Small volume liquid dosage forms
	1.1.2.3. Solid dosage forms and implants
	1.1.2.4. Soft dosage forms
	1.1.2.5. Other products subject to terminal sterilization
	1.1.3. Release quality control (batch release)
1.2	Non-sterile products
X	1.2.1. Non-sterile products (processing operations for manufacturing of the following dosage forms):
	1.2.1.1. Hard shell capsules
	1.2.1.2. Soft shell capsules
	1.2.1.3. Chewable dosage forms
	1.2.1.4. Impregnated dosage forms
	1.2.1.5. Liquid dosage forms for external use
	1.2.1.6. Liquid dosage forms for internal use
	1.2.1.7. Medical gases
	1.2.1.8. Other solid dosage forms
	1.2.1.9. Pressurized medicinal products
	1.2.1.10. Radionuclide generating products
	1.2.1.11. Soft dosage forms
	1.2.1.12. Suppositories
X	1.2.1.13. Tablets: tablets
	1.2.1.14. Transdermal patches

000003010

GMP/EAEU/RU/00925-2023

	1.2.1.15. Other non-sterile medicinal products
X	1.2.2. Release quality control (batch certification)
1.3	Biological medicinal products
	1.3.1. Biological medicinal products:
	1.3.1.1. Blood products
	1.3.1.2. Immunobiological products
	1.3.1.3. Products based on somatic cells (products for somatic cell therapy)
	1.3.1.4. Gene therapy products
	1.3.1.5. Biotechnological products
	1.3.1.6. Products derived from animal sources or human organs (tissues)
	1.3.1.7. Tissue engineering products
	1.3.1.8. Other biological medicinal products
	1.3.2. Release control (batch certification) (list of product types):
	1.3.2.1. Blood products
	1.3.2.2. Immunobiological products
	1.3.2.3. Products based on somatic cells (products for somatic cell therapy)
	1.3.2.4. Gene therapy products
	1.3.2.5. Biotechnological products
	1.3.2.6. Products derived from animal sources or human organs (tissues)
	1.3.2.7. Tissue engineering products
	1.3.2.8. Other biological medicinal products
1.4	Other medicinal products or manufacturing activities
X	1.4.1. Manufacture:
	1.4.1.1. Herbal products
	1.4.1.2. Homeopathic products
X	1.4.1.3. Other products: other groups of medicinal products: tablets

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**
GMP/EAEU/RU/00925-2023

	1.4.2 Sterilization of drug substances, excipients, finished products:
	1.4.2.1. Filtration
	1.4.2.2. Dry heat sterilization
	1.4.2.3. Steam sterilization
	1.4.2.4. Chemical sterilization
	1.4.2.5. Gamma irradiation sterilization
	1.4.2.6. Electronic irradiation sterilization
	1.4.3. Other
1.5	Packaging
X	1.5.1. Primary packaging
	1.2.1.1. Hard shell capsules
	1.2.1.2. Soft shell capsules
	1.2.1.3. Chewable dosage forms
	1.2.1.4. Impregnated dosage forms
	1.2.1.5. Liquid dosage forms for external use
	1.2.1.6. Liquid dosage forms for internal use
	1.2.1.7. Medical gases
	1.2.1.8. Other solid dosage forms
	1.2.1.9. Pressurized medicinal products
	1.2.1.10. Radionuclide generating products
	1.2.1.11. Soft dosage forms
	1.2.1.12. Suppositories
X	1.2.1.13. Tablets: tablets
	1.2.1.14. Transdermal patches
	1.2.1.15. Other non-sterile medicinal products
X	1.5.2. Secondary packaging
1.6.	Quality control
	1.6.1. Microbiological testing: sterility
X	1.6.2. Microbiological testing: microbiological purity
X	1.6.3. Chemical (physical) testing
	1.6.4. Biological testing
2. IMPORT OF MEDICINAL PRODUCTS	
2.1	Quality control of imported medicinal products
	2.1.1. Microbiological testing: sterility
	2.1.2. Microbiological testing: microbiological purity
	2.1.3. Chemical (physical) testing
	2.1.4. Biological testing
2.2	Certification of a batch of imported medicinal products

000003011

GMP/EAEU/RU/00925-2023

	2.2.1 Sterile products:
	2.2.1.1. Manufactured under aseptic conditions
	2.2.1.2. Subject to terminal sterilization
	2.2.2 Non-sterile products:
	2.2.3. Biological medicinal products:
	2.2.3.1. Blood products
	2.2.3.2. Immunobiological products
	2.2.3.3. Products based on somatic cells (products for somatic cell therapy)
	2.2.3.4. Gene therapy products
	2.2.3.5. Biotechnological products
	2.2.3.6. Products derived from animal sources or human organs (tissues)
	2.2.3.7. Tissue engineering products
	2.2.3.8. Other biological medicinal products
2.3	Other import activities
	2.3.1. Physical importation site
	2.3.2. Import of intermediate products subject to further processing
	2.3.3. Other
MANUFACTURING OPERATIONS – DRUG SUBSTANCES	
Drug substance(s):	
3.1	Manufacture of drug substances by chemical synthesis
	3.1.1. Manufacture of drug substance intermediates
	3.1.2. Manufacture of crude drug substance
	3.1.3. Salt formation (purification): please specify (e.g., recrystallization)
	3.1.4. Other

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**
GMP/EAEU/RU/00925-2023

3.2	Manufacture of drug substances by isolating them from natural sources
	3.2.1. Isolation of drug substances from herbal sources
	3.2.2. Isolation of drug substances from animal sources
	3.2.3. Isolation of drug substances from human organs (tissues)
	3.2.4. Isolation of drug substances from mineral sources
	3.2.5. Modification of the isolated drug substance
	3.2.6. Purification of the isolated drug substance
	3.2.7. Other
3.3	Manufacture of drug substances using biological processes
	3.3.1. Fermentation
	3.3.2. Manufacture using cell cultures
	3.3.3. Selection (purification)
	3.3.4. Modification
	3.3.5. Other
3.4	Manufacture of sterile drug substances
	3.4.1. Drug substances manufactured under aseptic conditions
	3.4.2. Drug substances subjected to terminal sterilization
3.5	Terminal stages of manufacture of drug substances
	3.5.1. Physical processing stages
	3.5.2. Primary packaging
	3.5.3. Secondary packaging
	3.5.4. Other
3.6	Quality control
	3.6.1. Physical (chemical) testing
	3.6.2. Microbiological testing (including sterility testing)
	3.6.3. Microbiological testing (excluding sterility testing)
	3.6.4. Biological testing

000003012

GMP/EAEU/RU/00925-2023

4. OTHER OPERATIONS – DRUG SUBSTANCES

Limitations or explanatory notes concerning the scope of the certificate:

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

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Total Records 1 to 1 of 1

Download

Certificate Number	GMPC or Non-compliance	Site Details	Country	Inspection Date
UK GMP 8913 Insp_GMP 8913/12228-0008[H]	GMPC	WOCKHARDT LIMITED , 87/A SILVER INDUSTRIAL ESTATE, BHIMPORE, NANI DAMAN, DAMAN, IN-396210, INDIA	INDIA	17/12/2018

Due to the restrictions caused by COVID-19, the period of validity GMP and GDP certificates issued by MHRA is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. MHRA reserve the right to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.



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EURASIAN ECONOMIC UNION

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**

CERTIFICATE

OF CONFORMITY OF MANUFACTURING OF MEDICINAL PRODUCTS TO THE
REQUIREMENTS OF THE GOOD MANUFACTURING PRACTICE REGULATIONS OF
THE EURASIAN ECONOMIC UNION

No. GMP/EAEU/RU/00925-2023

Effective from 07.07.2023 to 06.07.2026

Issued according to results of performance of a pharmaceutical inspection in
accordance with the Regulation for Performing Pharmaceutical Inspections
approved with Resolution of the Council of the Eurasian Economic Commission
No.83 of November 3, 2016

Ministry of Industry and Commerce of the Russian Federation
(Minpromtorg of Russia)

(full and abbreviated name of the authorized body)

hereby confirms the following:

the pharmaceutical inspection of the following entity has been performed:

Wockhardt Limited

(full name of the manufacturer)

Plot No.87-A, Silver Industrial Estate, Bhimpore, Nani Daman 396 210, India

(address of the manufacturing site)

on the basis of application for issuance of a certificate of conformity of the
manufacturer (non-resident manufacturer) of medicinal products for medical use to
the requirements of the Good Manufacturing Practice Regulations of the Eurasian
Economic Union No.299 of November 29, 2022.

Based on the information obtained during the inspections, the last of which was
performed from 03.07.2023 to 07.07.2023, it was established that this
pharmaceutical manufacturing site complies with the requirements of the Good
Manufacturing Practice Regulations of the Eurasian Economic Union, equivalent to
the Principles and Guidelines of the European Union on Good Manufacturing
Practice on medicinal products for medical and veterinary use and the principles of
the Pharmaceutical Inspection Cooperation System (PIC/S).

000001007

This certificate shall display the status of the manufacturing site as of the time of the pharmaceutical inspection and, more than 3 years after the date of the last day of the last inspection, it can no longer be considered a document indicating the status of conformity. The effective term of the certificate may be reduced by applying appropriate risk management principles if an appropriate entry is made in the “Limitations or explanatory notes regarding the scope of this certificate” field.

The certificate shall be deemed valid if all its sheets (both main sheets and additional sheets) are presented.

The authenticity of this certificate can be checked in the database of the Ministry of Industry and Trade of Russia.

If the certificate is not presented in the specified database, the authorized body that has issued it should be contacted.

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**
GMP/EAEU/RU/00925-2023

X	Medicinal products for medical use
☐	Medicinal products for clinical studies (trials)
Code	Name
I. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS	
1.1	Sterile products
	1.1.1. Manufactured under aseptic conditions (processing operations for the following dosage forms):
	1.1.1.1. Large volume liquid dosage forms
	1.1.1.2. Small volume liquid dosage forms
	1.1.1.3. Lyophilisates
	1.1.1.4. Solid dosage forms and implants
	1.1.1.5. Soft dosage forms
	1.1.1.6. Other products manufactured under aseptic conditions
	1.1.2. Products subject to terminal sterilization (processing operations for the following dosage forms):
	1.1.2.1. Large volume liquid dosage forms
	1.1.2.2. Small volume liquid dosage forms
	1.1.2.3. Solid dosage forms and implants
	1.1.2.4. Soft dosage forms
	1.1.2.5. Other products subject to terminal sterilization
	1.1.3. Release quality control (batch release)
1.2	Non-sterile products
X	1.2.1. Non-sterile products (processing operations for manufacturing of the following dosage forms):
	1.2.1.1. Hard shell capsules
	1.2.1.2. Soft shell capsules
	1.2.1.3. Chewable dosage forms
	1.2.1.4. Impregnated dosage forms
	1.2.1.5. Liquid dosage forms for external use
	1.2.1.6. Liquid dosage forms for internal use
	1.2.1.7. Medical gases
	1.2.1.8. Other solid dosage forms
	1.2.1.9. Pressurized medicinal products
	1.2.1.10. Radionuclide generating products
	1.2.1.11. Soft dosage forms
	1.2.1.12. Suppositories
X	1.2.1.13. Tablets: tablets
	1.2.1.14. Transdermal patches

000003010

	1.2.1.15. Other non-sterile medicinal products
X	1.2.2. Release quality control (batch certification)
1.3	Biological medicinal products
	1.3.1. Biological medicinal products:
	1.3.1.1. Blood products
	1.3.1.2. Immunobiological products
	1.3.1.3. Products based on somatic cells (products for somatic cell therapy)
	1.3.1.4. Gene therapy products
	1.3.1.5. Biotechnological products
	1.3.1.6. Products derived from animal sources or human organs (tissues)
	1.3.1.7. Tissue engineering products
	1.3.1.8. Other biological medicinal products
	1.3.2. Release control (batch certification) (list of product types):
	1.3.2.1. Blood products
	1.3.2.2. Immunobiological products
	1.3.2.3. Products based on somatic cells (products for somatic cell therapy)
	1.3.2.4. Gene therapy products
	1.3.2.5. Biotechnological products
	1.3.2.6. Products derived from animal sources or human organs (tissues)
	1.3.2.7. Tissue engineering products
	1.3.2.8. Other biological medicinal products
1.4	Other medicinal products or manufacturing activities
X	1.4.1. Manufacture:
	1.4.1.1. Herbal products
	1.4.1.2. Homeopathic products
X	1.4.1.3. Other products: other groups of medicinal products: tablets

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**
GMP/EAEU/RU/00925-2023

	1.4.2 Sterilization of drug substances, excipients, finished products:
	1.4.2.1. Filtration
	1.4.2.2. Dry heat sterilization
	1.4.2.3. Steam sterilization
	1.4.2.4. Chemical sterilization
	1.4.2.5. Gamma irradiation sterilization
	1.4.2.6. Electronic irradiation sterilization
	1.4.3. Other
1.5	Packaging
X	1.5.1. Primary packaging
	1.2.1.1. Hard shell capsules
	1.2.1.2. Soft shell capsules
	1.2.1.3. Chewable dosage forms
	1.2.1.4. Impregnated dosage forms
	1.2.1.5. Liquid dosage forms for external use
	1.2.1.6. Liquid dosage forms for internal use
	1.2.1.7. Medical gases
	1.2.1.8. Other solid dosage forms
	1.2.1.9. Pressurized medicinal products
	1.2.1.10. Radionuclide generating products
	1.2.1.11. Soft dosage forms
	1.2.1.12. Suppositories
X	1.2.1.13. Tablets: tablets
	1.2.1.14. Transdermal patches
	1.2.1.15. Other non-sterile medicinal products
X	1.5.2. Secondary packaging
1.6.	Quality control
	1.6.1. Microbiological testing: sterility
X	1.6.2. Microbiological testing: microbiological purity
X	1.6.3. Chemical (physical) testing
	1.6.4. Biological testing
	2. IMPORT OF MEDICINAL PRODUCTS
2.1	Quality control of imported medicinal products
	2.1.1. Microbiological testing: sterility
	2.1.2. Microbiological testing: microbiological purity
	2.1.3. Chemical (physical) testing
	2.1.4. Biological testing
2.2	Certification of a batch of imported medicinal products

000003011

	2.2.1 Sterile products:
	2.2.1.1. Manufactured under aseptic conditions
	2.2.1.2. Subject to terminal sterilization
	2.2.2 Non-sterile products:
	2.2.3. Biological medicinal products:
	2.2.3.1. Blood products
	2.2.3.2. Immunobiological products
	2.2.3.3. Products based on somatic cells (products for somatic cell therapy)
	2.2.3.4. Gene therapy products
	2.2.3.5. Biotechnological products
	2.2.3.6. Products derived from animal sources or human organs (tissues)
	2.2.3.7. Tissue engineering products
	2.2.3.8. Other biological medicinal products
2.3	Other import activities
	2.3.1. Physical importation site
	2.3.2. Import of intermediate products subject to further processing
	2.3.3. Other
MANUFACTURING OPERATIONS – DRUG SUBSTANCES	
Drug substance(s):	
3.1	Manufacture of drug substances by chemical synthesis
	3.1.1. Manufacture of drug substance intermediates
	3.1.2. Manufacture of crude drug substance
	3.1.3. Salt formation (purification): please specify (e.g., recrystallization)
	3.1.4. Other

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

**MINISTRY OF INDUSTRY AND COMMERCE
OF THE RUSSIAN FEDERATION**
GMP/EAEU/RU/00925-2023

3.2	Manufacture of drug substances by isolating them from natural sources
	3.2.1. Isolation of drug substances from herbal sources
	3.2.2. Isolation of drug substances from animal sources
	3.2.3. Isolation of drug substances from human organs (tissues)
	3.2.4. Isolation of drug substances from mineral sources
	3.2.5. Modification of the isolated drug substance
	3.2.6. Purification of the isolated drug substance
	3.2.7. Other
3.3	Manufacture of drug substances using biological processes
	3.3.1. Fermentation
	3.3.2. Manufacture using cell cultures
	3.3.3. Selection (purification)
	3.3.4. Modification
	3.3.5. Other
3.4	Manufacture of sterile drug substances
	3.4.1. Drug substances manufactured under aseptic conditions
	3.4.2. Drug substances subjected to terminal sterilization
3.5	Terminal stages of manufacture of drug substances
	3.5.1. Physical processing stages
	3.5.2. Primary packaging
	3.5.3. Secondary packaging
	3.5.4. Other
3.6	Quality control
	3.6.1. Physical (chemical) testing
	3.6.2. Microbiological testing (including sterility testing)
	3.6.3. Microbiological testing (excluding sterility testing)
	3.6.4. Biological testing

000003012

4. OTHER OPERATIONS – DRUG SUBSTANCES
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Limitations or explanatory notes concerning the scope of the certificate:

Deputy Minister

(signed)

E. G. Prieszheva

(Seal of the Ministry of Industry and Commerce of Russia)

September 6, 2023

Date of issue of the certificate

No. DCD/D&D/LA/2023-2024/12072
U.T. Administration of Dadra & Nagar Haveli
and Daman & Diu,
Assistant Drugs Controller &
Licensing Authority,
Drugs Control Department,
Primary Health Centre,
Moti Daman – 396 220.

Dated: - 16 /12/2023.

To
✓ **M/S. WOCKHARDT LIMITED.**
Survey No. 87-A,
Silver Industrial Estate,
Bhimpore, Daman – 396 210.

SUB: - GRANT OF SCHEDULE M - GMP CERTIFICATE - REG.

The subject inspection was carried out by the Drugs Inspector of this office on 16/11/2023 for issue of **REVISED SCHEDULE M -GMP CERTIFICATE** as per stipulated guidelines of Drugs & Cosmetics Act and Rules, 1945 and he has recommended for the Category of Tablets (coated & uncoated), Capsules & Small Volume Parenterals.



(S. Asker Ali) IAS
Assistant Drugs Controller /
Licensing Authority,
UT of Dadra & Nagar Haveli and
Daman & Diu,
Daman.

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU
ASSISTANT DRUGS CONTROLLER (I/C) &
LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE
MOTI DAMAN-396220

NO. DCD/D&D/LA/2023-2024/12073

DATED: 16 /12/2023

SCHEDULE M - G.M.P CERTIFICATE

THIS IS TO CERTIFY THAT M/S. WOCKHARDT LIMITED., SITUATED AT SURVEY NO. 87-A, SILVER INDUSTRIAL ESTATE, BHIMPORE, DAMAN- 396210 ARE HOLDING LICENCE IN FORM 25 AND FORM 28 BEARING LICENCE NO. DD/61 AND DD/62 DATED 18/10/1994 RENEWED UPTO 31/12/2026 FOR MANUFACTURER FOR SALE OR DISTRIBUTION OF DRUGS APPROVED BY THIS DEPARTMENT. THE FIRMS IS SUBJECTED TO PERIODICAL INSPECTION BY THIS DEPARTMENT.

THE FIRM, BY AND LARGE, IS FOLLOWING GOOD MANUFACTURING PRACTICES AS STIPULATED UNDER THE PROVISIONS OF REVISED SCHEDULE "M" OF DRUGS AND COSMETICS RULES, 1945 FOR THE CATEGORY OF TABLETS (COATED & UNCOATED), CAPSULES & SMALL VOLUME PARENTERALS.

THE FIRM SHOULD, HOWEVER CARRY OUT SELF INSPECTION FROM TIME TO TIME TO ENSURE THAT THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICES ARE COMPLIED WITH.

THIS CERTIFICATE IS VALID FOR ONE YEAR FROM THE DATE OF ISSUE.



(S. ASKER ALI) IAS
ASSISTANT DRUGS CONTROLLER &
LICENSING AUTHORITY,
UT OF DADRA & NAGAR HAVELI &
DAMAN & DIU,
DAMAN.

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU
ASSISTANT DRUGS CONTROLLER &
LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION,
OLD GOVT. PRIMARY SCHOOL, VARLIWAD, JAMPORE,
MOTI DAMAN - 396 220

No. DCA/D&D/LA/2025-2026/ 2530

Dated: - 30 /07/2025.

G. L. P. CERTIFICATE

This is to certify that **Wockhardt Limited.**, situated at 87-A, Silver Industrial Estate, Bhimpore, Nani Daman-396210, INDIA is holding valid manufacturing license in Form No. 25 & Form No. 28 bearing license No. **DD/61 & DD/62 valid up to 31/12/2026** for manufacture and sale or distribution of drugs specified in schedule C and C (1) excluding those specified in schedule X.

1. The firm is having well equipped Quality Control Laboratory for testing of drugs: Tablets (coated & uncoated), Capsules & Small Volume Parenterals dosage form and following Good Laboratory Practices, as stipulated under the provisions "Revised Schedule L-1" of drugs and Cosmetic Rules 1945.
2. This certificate is issued on the request of the firm for submitting the same to various Government Hospital, Corporations, Defense and Supply to Non-regulated markets and institutions for tender purpose.
3. This certificate is valid for **One Year** from the date of issue.



To
Wockhardt Limited.
87-A, Silver Industrial Estate,
Bhimpore, Nani Daman-396210, INDIA

Sd/-
Assistant Drugs Controller &
Licensing Authority,
UT of Dadra & Nagar Haveli and
Daman & Diu,
Daman.

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN AND DIU
 ASSISTANT DRUGS CONTROLLER (I/C) &
 LICENSING AUTHORITY
 DRUGS CONTROL DEPARTMENT
 PRIMARY HEALTH CENTRE
 MOTI DAMAN-396 220

NO. DCD/D&D/LA/2023-2024/6833

DATED: 03/07/2023.

WHO-GMP CERTIFICATE

THIS IS TO CERTIFY THAT *M/S. WOCKHARDT LIMITED.*, PLOT NO. 87-A, SILVER INDUSTRIAL ESTATE, BHIMPORE, NANI DAMAN - 396 210, INDIA IS HOLDING VALID DRUG MANUFACTURING LICENCES IN *FORM NO. 25 & IN FORM NO. 28*, BEARING LICENCE NO. *DD/61 & DD/62*, DATED 18/10/1994 RESPECTIVELY, ISSUED BY THIS ADMINISTRATION UNDER THE PROVISIONS OF DRUGS & COSMETICS ACT, 1940 AND RULES THEREUNDER. UNDER THE SAID LICENCES THE FIRM IS PERMITTED TO MANUFACTURE AND SELL THEIR PRODUCTS COVERED UNDER THE CATEGORIES OF GENERAL: TABLETS, CAPSULES AND SMALL VOLUME PARENTERALS.

THE FIRM HAS EMPLOYED COMPETENT PERSONS IN MANUFACTURING AND QUALITY CONTROL DEPARTMENTS. THE FIRM IS FOLLOWING *GOOD MANUFACTURING PRACTICES AS PER WORLD HEALTH ORGANIZATION RECOMMENDATIONS* IN THE MANUFACTURING AND TESTING OF THE SAID CATEGORIES OF PRODUCTS GENERAL: TABLETS, CAPSULES AND SMALL VOLUME PARENTERALS.

THE MANUFACTURING PLANT IS SUBJECT TO REGULAR INSPECTION BY THE COMPETENT AUTHORITY UNDER THE ACT.

THIS CERTIFICATE IS VALID UP TO THREE YEARS FROM THE DATE OF ISSUE.



(DR. DHARMESH AGRAWAL)
 ASSISTANT DRUGS CONTROLLER (I/C) &
 LICENSING AUTHORITY
 UT OF DADRA & NAGAR HAVELI AND
 DAMAN & DIU
 DAMAN



File No. WZ1-11011(11)/24/2026-eoffice (36656)

By: E-mail only

Date: 07.07.2026

To,

The Assistant Drugs Controller & Licensing Authority,
UT of Dadra & Nagar Haveli and Daman & Diu, Daman,
Drugs Control Department, Moti Daman-396220.

Subject: Compliance verification report of M/s Wockhardt Limited, Survey No. 87-A, Silver Industrial Estate, Bhimpore, Nani Daman, Daman for grant and revalidation of COPP under WHO certification Scheme- reg.

References:

1. Firm's ONLS application vide no. DD/WHOGMP/2026/00048 dt. 05.05.2026.
2. This office letter vide no. WZ1-11011(11)/33/2025-eoffice dated 21.05.2026
3. Joint inspection report dated 28.05.2026 and 29.05.2026.
4. Compliance dated 25.06.2026 submitted by the firm and received to this office vide e-mail dated 25.06.2026.

Sir,

With reference to subject cited above, this is to inform you that the subject firm was jointly inspected comprising of Drugs Inspectors of this office and DCA, Daman on 28.05.2026 and 29.05.2026 for grant and revalidation of COPP under WHO-GMP Certification Scheme for applied products. The joint inspection team reported various shortcomings/deficiencies which were communicated to firm for submission of compliance report along with supporting documents.

Firm has submitted compliance report / CAPA along with supporting documents vide ref. no. 4 which were desktop reviewed by the Drugs Inspectors of this office. It is reported that firm has submitted acceptable level of compliance / CAPA along with supporting documents for reported observations.

In view of above, it is recommended that the firm's application for grant and revalidation of the Certificate of Pharmaceutical Product (COPP) under the WHO-GMP Certification Scheme for the applied products listed in the Annexure-I and II may be considered.

Further, it is informed that the firm shall obtain the requisite Export No Objection Certificate (Export NOC) for the products a) Paracetamol 500mg and Caffeine 65mg b) Aspirin, Paracetamol & Caffeine c) Paracetamol 500mg Capsules and d) Aspirin 75mg Gastro-resistant tablets prior to obtaining the COPP from the Drugs Control Department (DCD), Daman, and before commercializing these products for export purpose.

This is for your kind information and necessary action.

Encl.: Compliance verification report.

Yours faithfully,

SANTOSH
VITTHALRAO
INDRAKSHA

Deputy Drugs Controller (India)
CDSCO, West Zone, Mumbai

Digitally signed by SANTOSH
VITTHALRAO INDRAKSHA
Date: 2026.07.07 14:47:31
+05'30'

Copy to: M/s Wockhardt Limited, Survey No. 87-A, Silver Industrial Estate, Bhimpore, Nani Daman, Daman – 396210, (Jsingh@wockhardt.com, Prakashtandel@wockhardt.com)

(Hindi version next Page and English version will prevail)



File No. WZ1-11011(11)/24/2026-eoffice (36656)

By: E-mail only

Date: 07.07.2026

सेवा में,

सहायक औषधि नियंत्रक एवं अनुज्ञापन प्राधिकारी,
संघ राज्य क्षेत्र दादरा एवं नगर हवेली तथा दमन एवं दीव, दमन,
औषधि नियंत्रण विभाग, मोती दमन – 396220.

विषय: मैसर्स Wockhardt Limited, Survey No. 87-A, Silver Industrial Estate, Bhimpore, Nani Daman, Daman के संबंध में WHO प्रमाणन योजना के अंतर्गत COPP के अनुदान एवं पुनर्वैधीकरण हेतु अनुपालन सत्यापन प्रतिवेदन।

संदर्भ:

1. फर्म का ONLS आवेदन संख्या DD/WHOGMP/2026/00048 दिनांक 05.05.2026।
2. इस कार्यालय का पत्र संख्या WZ1-11011(11)/33/2025-eoffice दिनांक 21.05.2026।
3. दिनांक 28.05.2026 एवं 29.05.2026 का संयुक्त निरीक्षण प्रतिवेदन।
4. फर्म द्वारा दिनांक 25.06.2026 को प्रस्तुत अनुपालन प्रतिवेदन, जो इस कार्यालय को दिनांक 25.06.2026 को ई-मेल के माध्यम से प्राप्त हुआ।

महोदय,

उपरोक्त विषय के संदर्भ में अवगत कराना है कि उक्त फर्म का WHO-GMP प्रमाणन योजना के अंतर्गत आवेदन किए गए उत्पादों हेतु Certificate of Pharmaceutical Product (COPP) के अनुदान एवं पुनर्वैधीकरण के लिए इस कार्यालय तथा औषधि नियंत्रण प्रशासन, दमन के औषधि निरीक्षकों द्वारा दिनांक 28.05.2026 एवं 29.05.2026 को संयुक्त निरीक्षण किया गया।

संयुक्त निरीक्षण दल द्वारा विभिन्न कमियों/अनुपालनहीनताओं का उल्लेख किया गया, जिन्हें आवश्यक सहायक दस्तावेजों सहित अनुपालन प्रतिवेदन प्रस्तुत करने हेतु फर्म को सूचित किया गया। फर्म द्वारा संदर्भ क्रमांक 4 के अनुसार अनुपालन प्रतिवेदन/सुधारात्मक एवं निवारक कार्यवाही (CAPA) आवश्यक सहायक दस्तावेजों सहित प्रस्तुत की गई, जिसका इस कार्यालय के औषधि निरीक्षकों द्वारा डेस्कटॉप परीक्षण (Desktop Review) किया गया। परीक्षण के उपरांत यह पाया गया कि फर्म द्वारा निरीक्षण के दौरान इंगित की गई कमियों के संबंध में स्वीकार्य स्तर का अनुपालन/CAPA तथा आवश्यक सहायक दस्तावेज प्रस्तुत किए गए हैं।

उपरोक्त के दृष्टिगत, WHO-GMP प्रमाणन योजना के अंतर्गत परिशिष्ट-I एवं परिशिष्ट-II में उल्लिखित आवेदनित उत्पादों के लिए Certificate of Pharmaceutical Product (COPP) के अनुदान एवं पुनर्वैधीकरण हेतु फर्म के आवेदन पर विचार किए जाने की अनुशंसा की जाती है। इसके अतिरिक्त, यह अवगत कराया जाता है कि फर्म को निम्नलिखित उत्पादों के लिए Drugs Control Department (DCD), Daman से COPP प्राप्त करने तथा इन उत्पादों का निर्यात हेतु व्यावसायीकरण (Commercialization) प्रारंभ करने से पूर्व आवश्यक Export No Objection Certificate (Export NOC) प्राप्त करना होगा— a) Paracetamol 500 mg and Caffeine 65 mg b) Aspirin, Paracetamol & Caffeine c) Paracetamol 500 mg Capsules d) Aspirin 75 mg Gastro-resistant Tablets

यह आपके संज्ञान एवं आवश्यक कार्यवाही हेतु प्रेषित है।

संलग्नक: अनुपालन सत्यापन प्रतिवेदन।

भवदीय,

SANTOSH
VITTHALRAO
INDRAKSHA
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SANTOSH VITTHALRAO
INDRAKSHA
Date: 2026.07.07
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उप औषधि नियंत्रक (भारत)
सीडीएससीओ, पश्चिम क्षेत्र, मुंबई

प्रतिलिपि:

मैसर्स Wockhardt Limited, Survey No. 87-A, Silver Industrial Estate, Bhimpore, Nani Daman, Daman – 396210
(E-mail: Jsingh@wockhardt.com, Prakashtandel@wockhardt.com)

(Daman Kadaiya)

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU
ASSISTANT DRUGS CONTROLLER (I/C) &
LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE
MOTI DAMAN-396220

=====

NO. DCD/D&D/LA/2022-2023/ 3035

=====

DATED: 17/03/2023

✓ TO

M/S. WOCKHARDT LIMITED.
SURVEY NO. 106/4-5-7,
DAMAN INDUSTRIAL ESTATE,
KADAIYA, DAMAN -396 210.

SUB: - DRUGS AND COSMETICS ACT, 1940 & RULES THEREUNDER
RETENTION OF LICENCE UNDER THE.....

I AM ENCLOSING HERewith THE LICENCE VALIDITY CERTIFICATE OF LICENCE BEARING NO. DD/206 & DD/207 GRANTED ON 22/12/1999 TO YOU ON FORM 25 & FORM 28 UNDER THE PROVISION OF DRUGS AND COSMETICS ACT, 1940 AND RULES THEREUNDER ALONG WITH LIST OF PRODUCTS AND LIST OF APPROVED TECHNICAL STAFF. FURTHER ENCLOSED HERewith LICENCE VALIDITY CERTIFICATE FOR THE PERIOD FROM 01/01/2023 TO 31/12/2027 I.E. FIVE YEARS ONLY.

ENCL: AS ABOVE.


(DR. DHARMESH AGRAWAL)
ASSISTANT DRUGS CONTROLLER (I/C) &
LICENSING AUTHORITY,
UT OF DADRA & NAGAR HAVELI AND
DAMAN & DIU
DAMAN

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU
ASSISTANT DRUGS CONTROLLER (I/C) &
LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE
MOTI DAMAN-396220

NO. DCD/D&D/LA/2022-2023/ 3036

DATED: 17/03/2023

LICENCE VALIDITY CERTIFICATE
(SEE RULE 72 AND 84 C)

REF: NO. NIL DATED 23/12/2022.

- 1) A LICENCE NO. DD/206 AND DD/207 GRANTED ON 22/12/1999 TO M/S. WOCKHARDT LIMITED; SITUATED AT SURVEY NO. 106/4-5-7, DAMAN INDUSTRIAL ESTATE, KADAIYA, DAMAN -396 210, INDIA, IN FORM 25 AND FORM 28 SHALL REMAIN PERPETUALLY VALID UPTO 31/12/2027 AS THE LICENCEE HAS DEPOSITED A LICENCE RETENTION FEE VIDE CHALLAN INVOICE NO. 002600 DATED 23/12/2022 AS PER THE DRUGS & COSMETICS RULES, 1945.
- 2) NAMES OF DRUGS: AS PER LIST ATTACHED.
- 3) NAMES OF APPROVED COMPETENT TECHNICAL STAFF: AS PER LIST ATTACHED.
- 4) FIRM SHALL COMPLY TO THE DRUGS & COSMETICS ACT, 1940 & RULES 1945 THEREUNDER.

DATED:

11 7 MAR 2023



(DR. DHARMESH AGRAWAL)

ASSISTANT DRUGS CONTROLLER (I/C) &
LICENSING AUTHORITY,
UT OF DADRA & NAGAR HAVELI AND
DAMAN & DIU
DAMAN

NOTE:

- 1) IN FORM 25 FOR PARAGRAPH 3, THE FOLLOWING PARAGRAPH SHALL RESPECTIVELY BE SUBSTITUTED, 3. "THE LICENCE UNLESS SOONER SUSPENDED OR CANCELLED SHALL REMAIN VALID PERPETUALLY. HOWEVER, THE COMPLIANCE WITH THE CONDITIONS OF LICENCE AND THE PROVISIONS OF THE DRUGS & COSMETICS ACT, 1940 (23 OF 1940) AND DRUGS AND COSMETICS RULES, 1945 SHALL BE ASSESSED NOT LESS THAN ONCE IN THREE YEARS OR AS NEEDED AS PER RISK BASED APPROACH".
- 2) IN FORM 28 FOR PARAGRAPH 4, THE FOLLOWING PARAGRAPH SHALL RESPECTIVELY BE SUBSTITUTED, "THE LICENCE, UNLESS SOONER SUSPENDED OR CANCELLED, SHALL REMAIN VALID PERPETUALLY. HOWEVER, THE COMPLIANCE WITH THE CONDITIONS OF LICENCE AND THE PROVISIONS OF THE DRUGS & COSMETICS ACT, 1940N (23 OF 1940) AND THE DRUGS AND COSMETICS RULES, 1945 SHALL BE ASSESSED NOT LESS THAN ONCE IN THREE YEARS OR AS NEEDED AS PER RISK BASED APPROACH".

Medicines and Healthcare Products Regulatory Agency

CERTIFICATE NUMBER : **UK GMP 8913 Insp GMP 8913/378537-0009**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :

The competent authority of United Kingdom confirms the following:

The manufacturer : **WOCKHARDT LIMITED**

Site address : **SURVEY NO. 106/4-5-7, KADAIYA, NANI DAMAN, IN-396210, India**

OMS Location :

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:

The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-12-20**, it is considered that it complies with :

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(3) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

2019-03-28

Name and signature of the authorised person of the
Competent Authority of United Kingdom

Confidential

Medicines and Healthcare Products Regulatory Agency

Tel : Confidential

Fax : Confidential

Certificate Number	GMPC or Non-compliance	Site Details	Country	Inspection Date
UK GMP 8913 Insp GMP 8913/378537-0009[H]	GMPC	WOCKHARDT LIMITED , SURVEY NO. 106/4-5-7, KADAIYA, NANI DAMAN, IN-396210, INDIA	INDIA	20/12/2018

Due to the restrictions caused by COVID-19, the period of validity GMP and GDP certificates issued by MHRA is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. MHRA reserve the right to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.

 Medicines & Healthcare products
Regulatory Agency

[Terms and Conditions](#) | [Privacy Notice](#)

No. DCA/D&D/LA/2026-2027/ **572**
U.T. Administration of Dadra & Nagar Haveli
and Daman & Diu,
Drugs Licensing Authority,
Drugs Control Administration,
Old Govt. Primary School,
Varliwad, Jampore,
Moti Daman - 396 220.

Dated: - **12**/05/2026.

TO
WOCKHARDT LIMITED.

Plot No. 106-4/5/7,
Daman Industrial Estate,
Kadaiya, Daman - 396 210.

SUB: - GRANT OF SCHEDULE M - GMP CERTIFICATE - REG.

The subject inspection was carried out by the Drugs officer of this office on **21 APR 2026** for issue of **REVISED SCHEDULE M -GMP CERTIFICATE** as per stipulated guidelines of Drugs & Cosmetics Act and Rules, 1945 and he has recommended for the Category of Tablets (Coated & Uncoated).

(Arava Gopi Karishna) IAS.
Secretary (Health)/
Drugs Licensing Authority,
UT of Dadra & Nagar Haveli and
Daman & Diu,
Daman.



U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU
DRUGS LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION
OLD GOVT. PRIMARY SCHOOL, VARLIWAD, JAMPORE,
MOTI DAMAN-396220

NO. DCA/D&D/LA/2026-2027/ 573

DATED: 12/05/2026

SCHEDULE M - G.M.P CERTIFICATE

THIS IS TO CERTIFY THAT **WOCKHARDT LIMITED.**, SITUATED AT PLOT NO. 106/4-5-7, DAMAN INDUSTRIAL ESTATE, KADAIYA, DAMAN- 396210 ARE HOLDING LICENCE IN **FORM 25 AND FORM 28** BEARING LICENCE NO. DD/206 AND DD/207 DATED 22/12/1999 RENEWED UPTO 31/12/2027 FOR MANUFACTURER FOR SALE OR DISTRIBUTION OF DRUGS APPROVED BY THIS DEPARTMENT. THE FIRMS IS SUBJECTED TO PERIODICAL INSPECTION BY THIS DEPARTMENT.

THE FIRM, BY AND LARGE, IS FOLLOWING **GOOD MANUFACTURING PRACTICES** AS STIPULATED UNDER THE PROVISIONS OF **REVISED SCHEDULE "M"** OF DRUGS AND COSMETICS RULES, 1945 FOR THE GENERAL CATEGORY OF MANUFACTURING OF GENERAL -TABLETS (COATED & UNCOATED).

THE FIRM SHOULD, HOWEVER CARRY OUT SELF INSPECTION FROM TIME TO TIME TO ENSURE THAT THE REQUIREMENTS OF GOOD MANUFACTURING PRACTICES ARE COMPLIED WITH.

THIS CERTIFICATE IS VALID FOR ONE YEAR FROM THE DATE OF ISSUE.



(ARAVA GOPIKRISHNA) IAS
SECRETARY (HEALTH)/
DRUGS LICENSING AUTHORITY,
UT OF DADRA & NAGAR HAVELI AND
DAMAN & DIU
DAMAN

U.T. ADMINISTRATION OF DADRA & NAGAR HAVELI AND DAMAN & DIU
ASSISTANT DRUGS CONTROLLER &
LICENSING AUTHORITY
DRUGS CONTROL ADMINISTRATION,
OLD GOVT. PRIMARY SCHOOL, VARLIWAD, JAMPORE,
MOTI DAMAN - 396 220

No. DCA/D&D/LA/2025-2026/2529

Dated: - 30 /07/2025.

G. L. P. CERTIFICATE

This is to certify that **Wockhardt Limited.**, situated at Plot No. 106-4/5/7, Daman Industrial Estate, Kadaiya, Nani Daman-396210, INDIA is holding valid manufacturing license in Form No. 25 & Form No. 28 bearing license No. **DD/206 & DD/207 valid up to 31/12/2027** for manufacture and sale or distribution of drugs specified in schedule C and C (1) excluding those specified in schedule X.

1. The firm is having well equipped Quality Control Laboratory for testing of drugs: Tablets and Capsules dosage form and following Good Laboratory Practices, as stipulated under the provisions "Revised Schedule L-1" of drugs and Cosmetic Rules 1945.
2. This certificate is issued on the request of the firm for submitting the same to various Government Hospital, Corporations, Defense and Supply to Non-regulated markets and institutions for tender purpose.
3. This certificate is valid for **One Year** from the date of issue.



To

Wockhardt Limited.
Plot No. 106-4/5/7,
Daman Industrial Estate,
Kadaiya, Nani Daman-396210, INDIA

Sd/-

Assistant Drugs Controller &
Licensing Authority,
UT of Dadra & Nagar Haveli and
Daman & Diu,
Daman.

(Ankleshwar)

EudraGMDP

MIA | GMP | API REG | WDA | GDP | Sites

Help

Wed 13 Dec 2023 10:20:18 BST

GMP Compliance Menu

Search

[GMP Certificates](#)[Non-Compliance Report](#)[Print Preview](#)[Print Preview \(Short version\)](#)[Back To Search](#)**National Agency For The Safety Of Medicine And Health Products**

CERTIFICATE NUMBER: 19MPP006HPT01

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER⁽¹⁾, ⁽²⁾

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:

The manufacturer: **Wockhardt**

Site address: **Plot No. 138, G.I.D.C. Industrial Estate, Dist. Bharuch, Ankleshwar, Gujarat, 393002, India**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-04-03**, it is considered that it complies with:

- The principles of GMP for active substances ⁽³⁾ referred to in Article 47 of Directive 2001/83/EC

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

⁽¹⁾ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

⁽²⁾ Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

⁽³⁾ These requirements fulfil the GMP recommendations of WHO.

Part 2

Manufacture of active substance. Names of substances subject to inspection:

DIACEREIN(en)

DEXTROMETHORPHAN HYDROBROMIDE(en)

ADENOSINE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: DIACEREIN

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.3 Salt formation / Purification steps:

3.5 General Finishing Steps

3.5.1 Physical processing steps:
Milling, blending & sifting

3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Active Substance: DEXTROMETHORPHAN HYDROBROMIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture of active substance intermediates

3.1.2 Manufacture of crude active substance

3.1.3 Salt formation / Purification steps:

3.5 General Finishing Steps

3.5.1 Physical processing steps:
Sieving & milling

3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3.6 Quality Control Testing

	3.6.1 Physical / Chemical testing
Active Substance: ADENOSINE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	General Finishing Steps
	3.5.1 Physical processing steps: Sieving & milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users):

Signatory : Mr Guillaume Renaud, Deputy Director of inspection division — The ANSM does not issue hard copies of good practices certificates

2019-08-13

Name and signature of the authorised person of the Competent Authority of France

Confidential

French National Agency for Medicines and Health Products Safety

Tel: **Confidential**

Fax: **Confidential**

The EudraGMP database is maintained and operated by the EMA. Access to the general public is granted in order to enhance availability of information related to the EMA mandate. The content of the database is provided by the National Competent Authorities (NCA) of the EEA. For this reason, the EMA accepts no responsibility or liability whatsoever (including but not limited to any direct or consequential loss or damage it might occur to you and/or any other third party) arising out of or in connection with the information on this database. Any questions about the content should be addressed to the relevant NCA. Please [click here](#) to get list of NCAs.

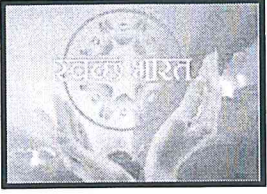
Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on [EMA's website](#)

[EMA © 2014. EudraGMP 6.5.1.4 build 2023/12/05 14:12]



No: WHO-GMP/25045665/ 14992 /B

Commissioner

Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar

Date :

03 APR 2025

To,
M/s. WOCKHARDT LIMITED,
PLOT NO. - 138, G.I.D.C., AT & POST - ANKLESHWAR,
ANKLESHWAR -393 002,
DIST.- BHARUCH

Sub :- Drugs & Cosmetics Act, 1940 & Rules thereunder.
Issue of copies of WHO-GMP Certificate

Sir,

Ref:- Your letter Dated : 20/02/2025

I send herewith World Health Organisation – Good Manufacturing Practices Certificate (WHO-GMP) in ONE copy as desired by you.

Yours faithfully,

for Commissioner
Food & Drugs Control Administration

No: WHO-GMP/25045665/

/B Gandhinagar Date

Copy forwarded to :-

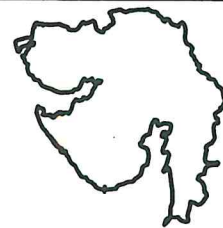
1. Assistant Commissioner, BHARUCH
2. Copy to Dy. Drugs Controller, CDSCO, Air Cargo Complex, Ahmedabad
3. G - Branch.

for Commissioner
Food & Drugs Control Administration



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA, PIN : 382010



Certificate No. : **25045665**

On the basis of the inspection carried out on **11-12/03/2025 & 02/04/2025** we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1 Name & Address of site : **WOCKHARDT LIMITED,**

PLOT NO. - 138, G.I.D.C., AT & POST - ANKLESHWAR,

CITY - ANKLESHWAR -393 002, DIST. – BHARUCH

GUJARAT STATE, INDIA

2 Manufacturer's Licence
number :

G/659

G/897

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs [API's]	General	Manufacturer

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until **02/04/2028** It becomes invalid if the activities and /or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration, Block
No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, India. – Pin :
382010

Name & function of : (Dr. H. G. KOSHIA)
responsible Person Commissioner

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : 03/02/2025



LIST OF PRODUCTS FOR RENEWAL OF COPP AS PER WHO GMP GUIDELINES (FOR EXPORT)
(Manufacturing License No.: G/659 in Form No. 25 and G/897 in Form No. 28)

Sr. No.	Product Name	Quality Standard
1. (a)	Dextromethorphan Hydrobromide	IP
(b)	Dextromethorphan Hydrobromide	USP
(c)	Dextromethorphan Hydrobromide	BP
(d)	Dextromethorphan Hydrobromide	JP
(e)	Dextromethorphan Hydrobromide	EP
(f)	Dextromethorphan Hydrobromide	BP / USP
2.	Epinephrine	USP
3. (a)	Tamsulosin Hydrochloride	EP
(b)	Tamsulosin Hydrochloride	USP
4. (a)	Adenosine	USP
(b)	Adenosine	EP
5. (a)	Nicardipine Hydrochloride	IH
(b)	Nicardipine Hydrochloride	USP
6. (a)	Azithromycin	USP
(b)	Azithromycin (Anhydrous)	EP
7. (a)	Nadifloxacin	IH
(b)	Nadifloxacin	IP
8. (a)	Donepezil Hydrochloride	IH
(b)	Donepezil Hydrochloride Monohydrate	USP
9.	Bethanechol Chloride	USP
10. (a)	Captopril	USP
(b)	Captopril	EP

For Wockhardt Limited


Ashees Vishnoi
Head - Quality




For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

03 APR 2025 To 02 APR 2028

Contd..2..

: 2 :

LIST OF PRODUCTS FOR RENEWAL OF COPP AS PER WHO GMP GUIDELINES (FOR EXPORT)
(Manufacturing License No.: G/659 in Form No. 25 and G/897 in Form No. 28)

Sr. No.	Product Name	Quality Standard
11. (a)	Diacerein	IH
(b)	Diacerein	EP
12.	Desvenlafaxine Succinate Monohydrate	IH
13.	Pidotimod	IH
14.	Fosaprepitant Dimeglumine	IH
15.	Levonadifloxacin L-Arginine Tetrahydrate	IH
16.	Alalevonadifloxacin Mesylate	IH
17.	Nafithromycin	IH

For Wockhardt Limited

Ashees Vishnoi
Head - Quality





For **Commissioner**
Food & Drugs Control Administration
Gujarat State, Gandhinagar

03 APR 2025 TO 02 APR 2028

Pharmaceuticals and Medical Devices Agency

Certificate for notification of GMP compliance inspection result

Name	General name	
	Commercial name	DEXTROMETHORPHAN HYDROBROMIDE POWDER 10%"TOWA" and one other item (As the attached sheet)
Name of applicant		TOWA PHARMACEUTICAL CO.,LTD.
Approval application or approval date		As the attached sheet
Application date of GMP compliance inspection		June 14, 2019 (Reiwa 1)
Name of Manufacturing site inspected		Wockhardt Limited
Address of Manufacturing site inspected		138,G.I.D.C.Estate,Ankleshwar -393 002,District Bharuch, Gujarat,India
Name of Manufacturer		Wockhardt Limited
Address of Manufacturer		Wockhardt Towers,Bandra- kurla Complex,Bandra(East), Mumbai-400 051, Maharashtra, India
License category of manufacture or category for accreditation of foreign manufacturer		Article 36, Paragraph 1, Item 4 of the Pharmaceutical Affairs Law, Enforcement Regulations
License number of manufacture or Site Accreditation number and date		AG12300150 October 29, 2019 (Reiwa 1)
Inspection result		As a result of the GMP compliance inspection by PMDA based on Article 14, Paragraph 6 of the Pharmaceutical Affairs Law, PMDA made judgments as no problem matters in particular.
Remarks		System Receipt No.: 5130108006205 Regarding the GMP compliance inspection for the API "Dextromethorphan Hydrobromide Hydrate" (MF Registration No. 220MF10108).

As mentioned above, it is herewith notified of the result of the GMP compliance inspection.

February 13th, 2020 (Japanese calendar: Reiwa 2)

Chairman of Pharmaceuticals and Medical Devices Agency

To: Minister of Ministry of Health, Labour and Welfare

Certificate for notification of GMP compliance inspection result_TOWA PHARMACEUTICAL CO., LTD.

COPY

5130108006205

(Exhibit)

Name		Approval application for partial changes date
General name	Commercial name	
	DEXTROMETHORPHAN HYDROBROMIDE POWDER 10% "TOWA"	June 22, 2017 (Heisei 29)
	P DEXTROMETHORPHAN HYDROBROMIDE TABLETS 15mg "TOWA"	June 22, 2017 (Heisei 29)

7-5/2013/EU/WC-0075
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated

07 OCT 2025

To

M/s. Wockhardt Limited
Plot No. 138, G.I.D.C, Ankleshwar,
Dist. -Bharuch -393002, Gujarat State, India

SUB:- Written Confirmation of **M/s. Wockhardt Limited, Plot No. 138, GIDC, Ankleshwar, Dist. -Bharuch -393002, Gujarat State, India** as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. **WC/RE/2025/10825** submitted to CDSCO, Ahmedabad Zone office on CDSCO Sugam Portal, and the recommendation received from DDC (I), Ahmedabad Zone on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions: -

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.
3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.
4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.
5. The Written Confirmation will be withdrawn in the events of non-compliance of Standards.
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non-Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.
8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.
9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
--	--	07 OCT 2025	02.07.2028
1	8	07 OCT 2025	02.07.2028

Yours faithfully,

Chandrashekar
06/10/25
Ranga Chandrashekar
Joint Drugs Controller (India)
चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
केंद्रीय औषधि मानक नियंत्रण संगठन (सुझातल), स्वास्थ्य सेवा महानिदेशालय
C.D.S.C.O.(HQ), Dte. General of Health Services
स्वास्थ्य और परिवार कल्याण मंत्रालय / Ministry of Health and Family Welfare
एन.डी.ए. भवन, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s. Wockhardt Limited**
Plot No. 138, G.I.D.C, Ankleshwar,
Dist. -Bharuch -393002, Gujarat State, India

2. Manufacturer's licence number: **G/659 and G/897**

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

as per list enclosed as Annexures

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 11.03.2025 & 12.03.2025

The Written Confirmation remains valid until: 02.07.2028

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**

FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: **Ranga Chandrashekar,**
Joint Drugs Controller (India)

E-mail: **ranga.cs@cdsco.nic.in;**

Telephone no.: **+91-11-23236965**

Fax no.: **+91-11-23236973**

Chandrashekar Ranga
06/10/25

Signature

चंद्रशेखर रंगा/Chandrashekar Ranga
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller(India)
केंद्रीय औषधि मानक नियंत्रण संगठन (मुद्रालय), स्वास्थ्य सेवा महाविद्यालय
C.D.S.C.O(HQ), Dir. General of Health Services
स्वास्थ्य और परिवार कल्याण विभाग / Ministry of Health and Family Welfare
आर.टी. रोड, कोटला रोड, नई दिल्ली-110002 / FDA Bhawan, Kotla Road, New Delhi-110002



07 OCT 2025



Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Wockhardt Limited
Plot No. 138, G.I.D.C, Ankleshwar,
Dist. -Bharuch -393002, Gujarat State, India

List of APIs:

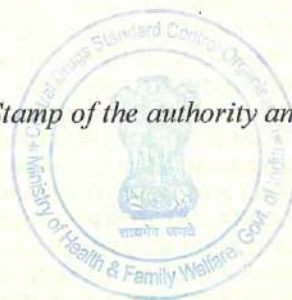
S. No.	Active Substance(s)	Activity(ies)
1.	Pidotimod IH	Manufacturing & Packing
2.	Adenosine USP/Ph.Eur.	Manufacturing & Packing
3.	Tamsulosin Hydrochloride USP/Ph.Eur.	Manufacturing & Packing
4.	Dextromethorphan Hydrobromide BP/USP/Ph.Eur.	Manufacturing & Packing
5.	Nicardipine Hydrochloride IH/USP	Manufacturing & Packing
6.	Bethanechol Chloride USP	Manufacturing & Packing
7.	Diacerein Ph.Eur.	Manufacturing & Packing
8.	Desvenlafaxine Succinate Monohydrate IH	Manufacturing & Packing

ITEM(S) EIGHT (08) ONLY

The Written Confirmation remains valid until: 02.07.2028

Chandrashekar
Signature 06/10/25
चंद्रशेखर रेगा/Chandrashekar
संयुक्त औषधि नियंत्रक (भारत) / Joint Drugs Controller (India)
स्वास्थ्य और परिवार कल्याण विभाग, स्वास्थ्य सेवा महानिदेशालय
The General of Health Services
Ministry of Health and Family Welfare
एन.डी.एम., बोडला रोड, संतिलुई-110002 / FDA Bawal, India

Stamp of the authority and date



U 7 OCT 2025

**Note: The Authorized Holder of this certificate is TOWA PHARMACEUTICAL CO., LTD.*

This certificate is for your backup and may not be used for any other purpose without TOWA's prior permission.

Certificate for GMP compliance inspection/review result

Name	General name	
	Commercial name	DEXTROMETHORPHAN HYDROBROMIDE TABLETS 15mg "TOWA"
Name of applicant		TOWA PHARMACEUTICAL CO., LTD.
Approval application or approval date		January 30, 2024 (Reiwa 6) Application for partial changes
Application date of GMP compliance inspection		January 31, 2024 (Reiwa 6)
Name of Manufacturing site inspected		Wockhardt Limited
Address of Manufacturing site inspected		138,G.I.D.C.Estate,Ankleshwar -393 002,District Bharuch, Gujarat,India
Name of Manufacturer		Wockhardt Limited
Address of Manufacturer		Wockhardt Towers,Bandra- kurla Complex,Bandra(East), Mumbai-400 051, Maharashtra, India
License category of manufacture or category for accreditation of foreign manufacturer		Non-sterile drugs
License number of manufacture or Site Accreditation number and date		AG12300150 October 29, 2019 (Reiwa 1)
Inspection/Review result		Conformed
Remarks		System Receipt No.: 5130608002617 Regarding the GMP compliance inspection for the API "Dextromethorphan Hydrobromide Hydrate" (MF Registration No. 303MF10152).

As mentioned above, it is herewith notified of the result of the GMP compliance inspection/review.

April 25, 2024 (Japanese calendar: Reiwa 6)

From Chairman of Pharmaceuticals and Medical Devices Agency (PMDA)

To TOWA PHARMACEUTICAL CO., LTD.

**Note: The Authorized Holder of this certificate is TOWA PHARMACEUTICAL CO., LTD..*

This certificate is for your backup and may not be used for any other purpose without TOWA's prior permission.

Certificate for GMP compliance inspection/review result

Name	General name	
	Commercial name	DEXTROMETHORPHAN HYDROBROMIDE TABLETS 15mg "TOWA"
Name of applicant		TOWA PHARMACEUTICAL CO., LTD.
Approval application or approval date		June 22, 2017 (Heisei 29) Approved
Application date of GMP compliance inspection		June 14, 2024 (Reiwa 6)
Name of Manufacturing site inspected		Wockhardt Limited
Address of Manufacturing site inspected		138,G.I.D.C.Estate,Ankleshwar -393 002,District Bharuch, Gujarat,India
Name of Manufacturer		Wockhardt Limited
Address of Manufacturer		Wockhardt Towers,Bandra- kurla Complex,Bandra(East), Mumbai-400 051, Maharashtra, India
License category of manufacture or category for accreditation of foreign manufacturer		Non-sterile drugs
License number of manufacture or Site Accreditation number and date		AG12300150 October 29, 2024 (Reiwa 6)
Inspection/Review result		Conformed
Remarks		System Receipt No.: 5130608019545 Regarding the GMP compliance inspection for the API “Dextromethorphan Hydrobromide Hydrate” (MF Registration No. 220MF10108).

As mentioned above, it is herewith notified of the result of the GMP compliance inspection/review.

September 4, 2025 (Japanese calendar: Reiwa 7)

From Chairman of Pharmaceuticals and Medical Devices Agency (PMDA)

To TOWA PHARMACEUTICAL CO., LTD.



UNCONTROLLED COPY

COMMISSIONER,

Food & Drugs Control Administration,

Block No.8, 1st floor, Dr. Jivraj Mehta Bhavan, Gandhinagar. - 382 010.

BY REGD.A.D. NO. LICENSE RETENTION/WOCKHARDT/2020/101035-37 /B, DATE :

To,
WOCKHARDT LTD.,
PLOT No. - 13B, G.I.D.C., ANKLESHWAR, DIST. - BHARUCH - 393 002

30 DEC 2021

SUB : Retention of licence for the Period : 2022 - 2026

Sir,

REF : Your application in Form No. 24 & 27, Dated : 22/11/2021

Licence having following details has been retention for a period of Five Years.

Details of Licence :

Form #	Licence #	Date of Licence	Retention Period		Category
			From	To	
25	G/659	31/05/1986	01/01/2022	31/12/2026	BULK DRUG
28	G/897	26/07/1994	01/01/2022	31/12/2026	BULK DRUG

Approved Technical Person (Manufacturing Section)

- 1 AS PER LIST APPROVED AND ANNEXED

Approved Technical Person (Testing Section)

- 1 AS PER LIST APPROVED AND ANNEXED

Further you are also permitted to get your raw materials and finished products tested at any govt. Approved public testing laboratories holding approval in form 37 under Drugs & Cosmetics Rules 1945 only for those tests which require sophisticated equipment's.

You are requested to get the products amended as per latest I.P. wherever applicable.

Further you are asked for compliance with respect to DCGI notification dated 07/08/2014 for products containing single ingredients (except for export purpose)

You are requested to apply for the Retention of the above license 3 months before their VALIDITY expires.

The above mentioned license need NOT be sent by the Dept.

Kindly acknowledge the receipt of this letter.

Subject to NO-CHANGE in Previous Constitution & Already approved Premises.

Technical Persons & Approved Products under said license are also retained till Dt. - 31/12/2026.

The License shall not claim any equities or rights in the property under reference on strength of this Retention Letter.

Yours faithfully,

For Commissioner,
Food & Drugs Control Administration.

- Encl:-** 1. Countersigned list of Products
2. Countersigned list of Technical Person.

Copy with a copy of approved list of products forwarded to :-

- 1) The Assistant Commissioner, BHARUCH
2) The Statistical Cell, (G-Branch)

UNCONTROLLED COPY

RETENTION OF LICENCE

Retention of Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedule C, C (1) and X

Certified that Licence in Form 25, No: G/659 Granted on the Date: 31/05/1986

To M/s. WOCKHARDT LTD.,

for the manufacture of the following categories of drugs being drugs other than those specified in Schedule C and C (1) and "X" to the Drugs and Cosmetics Rules, 1945 at the premises situated at PLOT No. - 138, G.I.D.C., ANKLESHWAR, DIST. - BHARUCH - 393 002

has been retained from: 01/01/2022 To 31/12/2026

Name(s) of drugs as retained (each item to be separately specified) : **As per list Approved & Annexed**
Names of approved competent technical staff as retained : **As per list Approved & Annexed**



(Dr. H. G. KOSHIA)
Commissioner,
Food & Drugs Control Administration,
Gujarat State

Date: 18/12/2021

Note: You are requested to apply for the Retention of the above licence in 3 months before its Validity Expires.

UNCONTROLLED COPY

RETENTION OF LICENCE

Retention of Licence to manufacture for sale (or for distribution) of drugs specified in Schedule C, C(1) excluding those specified in schedule X

Certified that Licence in Form **28**, No: **G/897** Granted on the Date: **26/07/1994**

To M/s. **WOCKHARDT LTD.,**

for the manufacture of the drugs Specified in Schedule C and C (1) excluding those specified in Schedule "X" to the Drugs and Cosmetics Rules, 1945, at the premises situated at **PLOT No. - 138, G.I.D.C., ANKLESHWAR, DIST. - BHARUCH - 393 002**

has been retained from: **01/01/2022** To **31/12/2026**

Name(s) of drugs as retained (each item to be separately specified) : **As per list Approved & Annexed**
Names of approved competent technical staff as retained : **As per list Approved & Annexed**



(Dr. H. G. KOSHIA)

Commissioner,
Food & Drugs Control Administration,
Gujarat State

Date: **18/12/2021**

Note: You are requested to apply for the Retention of the above licence in 3 months before its Validity Expires.

UNCONTROLLED COPY

WOCKHARDT | LIFE WINS

LIST OF PRODUCTS

List of Products to be manufactured by M/s Wockhardt Limited at Plot No.: 138, GIDC Estate, Ankleshwar, District Bharuch under License No.: G/659 in Form No.: 25.

Page No. 1 of 4

Sr. No.	Product Name	Quality Standard	Remarks
1.	Captopril	USP	For Export
2.	Captopril	EP	For Export
3.	Dextromethorphan Hydrobromide	IP	For Domestic
4.	Dextromethorphan Hydrobromide	USP	For Export
5.	Dextromethorphan Hydrobromide	BP	For Export
6.	Dextromethorphan Hydrobromide	JP	For Export
7.	Dextromethorphan Hydrobromide	EP	For Export
8.	Dextromethorphan Hydrobromide	USP	For Domestic Formulation use
9.	Dextromethorphan Hydrobromide	BP	For Domestic Formulation use
10.	Zolpidem Tartarate	EP	For Export
11.	Zolpidem Tartarate	BP	For Export
12.	Clopidogrel Bisulfate Form – I	IH	For Export
13.	Clopidogrel Bisulfate	USP	For Export
14.	Ziprasidone Hydrochloride	IH	For Export
15.	Ziprasidone Hydrochloride Monohydrate	USP	For Export
16.	Entacapone	IH	For Export
17.	Entacapone	USP	For Export
18.	Entacapone	EP	For Export
19.	Venlafaxine Hydrochloride	EP	For Export
20.	Granisetron Hydrochloride	EP	For Export
21.	Granisetron Hydrochloride	USP	For Export
22.	Tamsulosin Hydrochloride	IH	For Export
23.	Tamsulosin Hydrochloride	USP	For Export
24.	Tamsulosin Hydrochloride	EP	For Export
25.	Divalproex Sodium (Bulk)	IH	For Export
26.	Divalproex Sodium	USP	For Export

For Wockhardt Limited

Upendra Upadhyay
Upendra Upadhyay
 Authorized Signatory

For Commissioner

Food & Drugs Control Administration
 Gujarat State, Gandhinagar

Valid from 01.01.2022 to 31.12.2026

WOCKHARDT LIMITED • (Bulk Drug Division), Factory : Plot No. 138, GIDC Estate, Ankleshwar-393002, Dist. Bharuch, Gujarat, India
 T: 91-2646-661444 • F: 91-2646-661555 • Regd. Office : D-4 MIDC, Chikalthana, Aurangabad-431006, India • T: 91-240-6632222
 F: 91-240-2489219 • www.wockhardt.com • CIN: L24230MH1999PLC120720

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WOCKHARDT | LIFE WINS

Page No. 2 of 4

Sr. No.	Product Name	Quality Standard	Remarks
27.	Lansoprazole	USP	For Export
28.	Lansoprazole	EP	For Export
29.	Desloratadine	IH	For Export
30.	Desloratadine	IH	For Domestic
31.	Adenosine	USP	For Export
32.	Adenosine	EP	For Export
33.	Zoledronic Acid	IH	For Export
34.	Fluvastatin Sodium	USP	For Export
35.	Duloxetine Hydrochloride	IH	For Export
36.	Eszopiclone	IH	For Export
37.	Eszopiclone	IH	For Domestic
38.	Epinastine Hydrochloride	IH	For Export
39.	Pramipexole Dihydrochloride Monohydrate	IH	For Export
40.	Pramipexole Dihydrochloride Monohydrate	USP	For Domestic
41.	Brimonidine Tartrate	IH	For Export
42.	Tolterodine-L-Tartrate	IH	For Export
43.	Aripiprazole	IH	For Export
44.	Desvenlafaxine Succinate Monohydrate	IH	For Export
45.	Desvenlafaxine Succinate Monohydrate	IH	For Domestic
46.	Felodipine	EP	For Export
47.	Pioglitazone Hydrochloride	IH	For Export
48.	Pioglitazone Hydrochloride	USP	For Export
49.	Pantoprazole Sodium	IH	For Export
50.	Pantoprazole Sodium	USP	For Export
51.	Alfuzosin Hydrochloride	EP	For Export
52.	Alfuzosin Hydrochloride	USP	For Export



For Wockhardt Limited

Upendra Upadhyay
Upendra Upadhyay
 Authorized Signatory

029
 For Commissioner
 Food & Drugs Control Administration
 Gujarat State, Gandhinagar

Valid from 01.01.2022 to 31.12.2026

Sr. No.	Product Name	Quality Standard	Remarks
53.	Valacyclovir Hydrochloride	IH	For Export
54.	Valacyclovir Hydrochloride	USP	For Export
55.	Nicardipine Hydrochloride	IH	For Export
56.	Nicardipine Hydrochloride	USP	For Export
57.	Donepezil Hydrochloride	IH	For Export
58.	Donepezil Hydrochloride Monohydrate	USP	For Export
59.	Clopidogrel Hydrochloride	IH	For Export
60.	Chlorothiazide	USP	For Export
61.	Diacerein	IH	For Export
62.	Diacerein	EP	For Export
63.	Olanzapine	IH	For Export
64.	Fexofenadine Hydrochloride	USP	For Export
65.	Fexofenadine Hydrochloride	EP	For Export
66.	Fexofenadine Hydrochloride	IP	For Domestic
67.	Ropinirole Hydrochloride	IH	For Export
68.	Sitagliptin Phosphate	IH	For Export
69.	Sitagliptin Phosphate	USP	For Export
70.	Zonisamide	USP	For Export
71.	Cinacalcet Hydrochloride	IH	For Export
72.	Nadifloxacin	IH	For Export
73.	Nadifloxacin	IP	For Domestic
74.	Nepafenac	IH	For Export
75.	Nepafenac	IH	For Domestic
76.	Paliperidone	IH	For Export
77.	Palonosetron Hydrochloride	IH	For Export
78.	Palonosetron Hydrochloride	USP	For Export
79.	Palonosetron Hydrochloride	USP	For Domestic

For Wockhardt Limited

Upendra Upadhyay
Upendra Upadhyay
 Authorized Signatory

029
For Commissioner
 Food & Drugs Control Administration
 Gujarat State, Gandhinagar

Valid from 01.01.2022 to 31.12.2026

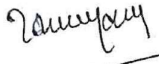
Sr. No.	Product Name	Quality Standard	Remarks
80.	Saxagliptin Hydrochloride	IH	For Domestic
81.	Saxagliptin Hydrochloride	IH	For Export
82.	Bethanechol Chloride	USP	For Export
83.	Pidotimod	IH	For Export
84.	Pidotimod	IH	For Domestic
85.	Oxybutynin Chloride	USP	For Export
86.	Tetrabenazine	IH	For Export
87.	Fosaprepitant Dimeglumine	IH	For Export
88.	Tapentadol Hydrochloride	IP	For Domestic
89.	Vildagliptin	IH	For Domestic
90.	Dextropropoxyphene Napsylate	IP	For Domestic
91.	Alalevonadifloxacin Mesylate	IH	For Export
92.	Alalevonadifloxacin Mesylate	IH	For Domestic
93.	Levonadifloxacin L-Arginine Tetrahydrate	IH	For Export
94.	Levonadifloxacin L-Arginine Tetrahydrate	IH	For Domestic
95.	Deferasirox	IH	For Domestic
96.	Deferasirox	IH	E-Export
97.	Deferasirox	EP	For Domestic
98.	Deferasirox	EP	E-Export

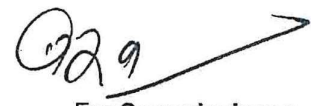
We declare that above are the only products to be manufactured by us at present. Any additions there to deletion there from shall not be done without prior permission of the Commissioner, Food & Drugs Control Administration, Gandhinagar, Gujarat.

We further declare that the products are safe for use in context of active ingredients, vehicles, excipients, additives and pharmaceutical aids in the formulation.

The above applied products do not fall in the Class-II and Class-IV of the BCS classification as per the notification GSR 327 (E) Date 3rd April 2017. Hence, we are exempted from the submission of bioequivalence data. In case if given information of applied products found false, erroneous, dummy or unfaithful, given permission is liable to cancellation without any prior notice.

For Wockhardt Limited


Upendra Upadhyay
Authorized Signatory


For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

Valid from 01.01.2022 to 31.12.2026

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WOCKHARDT | LIFE WINS

LIST OF PRODUCTS

List of Products to be manufactured by **M/s Wockhardt Limited** at Plot No.: 138, GIDC Estate, Ankleshwar, District Bharuch under **License No.: G/897 in Form No.: 28.**

Page No. 1 of 2

Sr. No.	Product Name	Quality Standard	Remarks
1.	Azithromycin	USP	For Export
2.	Azithromycin (Anhydrous)	EP	For Export
3.	Azithromycin Dihydrate	USP	For Export
4.	Clarithromycin	USP	For Export
5.	Clarithromycin	EP	For Export
6.	Sterile Cefuroxime Sodium	IP	For Domestic
7.	Sterile Cefuroxime Sodium	Ph. Eur.	For Export
8.	Sterile Cefuroxime Sodium	USP	For Export
9.	Sterile Cefotaxime Sodium	IP	For Domestic
10.	Sterile Cefotaxime Sodium	USP	For Export
11.	Sterile Cefotaxime Sodium	Ph. Eur.	For Export
12.	Sterile Ceftazidime	IP	For Domestic
13.	Sterile Ceftazidime	Ph. Eur.	For Export
14.	Cefepime for Injection (Sterile Bulk)	USP	For Export
15.	Sterile L-Arginine – For Captive Consumption	USP	For Export
16.	Sterile Cefepime Hydrochloride – For Captive Consumption	USP	For Export
17.	Cefuroxime Axetil	USP	For Export
18.	Cefuroxime Axetil	Ph. Eur.	For Export
19.	Sterile Ceftazidime Pentahydrate	USP	For Export
20.	Sterile Ceftriaxone Sodium	USP	For Export
21.	Ceftriaxone Sodium (Sterile)	EP	For Domestic Formulation use

For Wockhardt Limited

Upendra Upadhyay
Upendra Upadhyay
 Authorized Signatory



029
 For Commissioner
 Food & Drugs Control Administration
 Gujarat State, Gandhinagar

Valid from 01.01.2022 to 31.12.2026

WOCKHARDT LIMITED • (Bulk Drug Division), Factory : Plot No. 138, GIDC Estate, Ankleshwar-393002, Dist. Bharuch, Gujarat, India
 T: 91-2646-661444 • F: 91-2646-661555 • Regd. Office : D-4 MIDC, Chikalthana, Aurangabad-431006, India • T: 91-240-6632222
 F: 91-240-2489219 • www.wockhardt.com • CIN: L24230MH1999PLC120720

Sr. No.	Product Name	Quality Standard	Remarks
22.	Ceftazidime for Injection with Sodium Carbonate (Bulk Powder)	USP	For Export
23.	Epinephrine	USP	For Export
24.	Cefepime for Injection (Sterile Bulk) Sterile Mixture of Cefepime Hydrochloride USP and L-Arginine USP	USP	For Export
25.	Cyanocobalamin	IP	For Domestic
26.	Cyanocobalamin	USP	For Export
27.	Cyanocobalamin	BP	For Export
28.	Hydroxocobalamin Acetate	BP	For Export
29.	Mecobalamin	JP	For Export
30.	Cefixime	USP	For Export
31.	Cefixime	BP	For Export

We declare that above are the only products to be manufactured by us at present. Any additions there to deletion there from shall not be done without prior permission of the Commissioner, Food & Drugs Control Administration, Gandhinagar, Gujarat.

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For Wockhardt Limited


Upendra Upadhyay
Authorized Signatory


For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

Valid from 01.01.2022 to 31.12.2026

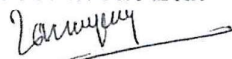
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WOCKHARDT LIFE WINS

LIST OF APPROVED TECHNICAL PERSONS

Sr No	Name of Employee	Qualification	Section	FDA Letter	
				No.	Date
A. FOR MANUFACTURING:					
1.	Mr A K Khatri	B. Sc.	Bulk Drug Manufacturing	60943	07.10.94
2.	Mr N J Patel	M. Sc.	Bulk Drug Manufacturing	67397	12.12.97
3.	Mr S R Patil	M. Sc.	Bulk Drug Manufacturing	30745	11.05.05
4.	Mr N V Borole	B. E. Chem.	Bulk Drug Manufacturing	30745	11.05.05
5.	Mr Rajeshkumar Singh	B. E. Chem.	Bulk Drug Manufacturing	30745	11.05.05
6.	Mr Sharad T Patil	B. Sc.	Bulk Drug Manufacturing	-	24.10.11
7.	Mr Chirag K Pandya	B. Sc. Chem.	Bulk Drug Manufacturing	-	24.10.11
8.	Mr Ranjeet kumar Thakur	B E Chem	Bulk Drug Manufacturing	79000	22.07.16
9.	Mr Jvalantkumar C Shukal	M. Sc. Chem	Bulk Drug Manufacturing	79000	22.07.16
10.	Mr Rajeshkumar P Sonavane	B. Sc. Chem	Bulk Drug Manufacturing	79000	22.07.16
11.	Mr Rohitkumar S Patel	B. Sc. Chem	Bulk Drug Manufacturing	79000	22.07.16
12.	Mr Kantilal L Patel	M. Sc. Chem	Bulk Drug Manufacturing	03220	17.09.18
13.	Mr Nikunj J Doshi	M. Sc. Chem	Bulk Drug Manufacturing	03220	17.09.18
B. FOR QUALITY CONTROL:					
14.	Mr S I Koya	B. Sc. Chem	Chemical & Physico Chemical testing.	44946	28.07.92
15.	Mr N I Patel	B. Sc.	Chemical & Physico Chemical testing.	34357	25.06.98
16.	Mr Kailash S Dhyani	B. Sc. Chem	Chemical & Physico Chemical testing.	79000	22.07.16
17.	Mr Kamleshkumar J Gajjar	M. Sc. Chem.	Chemical & Physico Chemical testing.	79000	22.07.16
18.	Mr Vishal Kumar Verma	M Sc Micro	Microbiology Assay Testing Section	03220	17.09.18

For Wockhardt Ltd.


 Authorised Signatory


 For, Commissioner
 Food & Drugs Control Administration
 Gujarat State, Gandhinagar.

11 JAN 2022

13 DEC 2026

UNCONTROLLED COPY

(Shendra)



MINISTRY OF HEALTH
BRAZILIAN HEALTH REGULATORY AGENCY

GOOD MANUFACTURING PRACTICES CERTIFICATE

The Brazilian Health Regulatory Agency (ANVISA), under its duties, certifies the company indicated below is periodically Inspected and monitored by the National Health Surveillance System and complies with the Good Manufacturing Practices guidelines given by Brazilian legislation, which is in accordance with the recommendations of the World Health Organization.

WOCKHARDT LIMITED

E-1/1, WOCKHARDT INFRASTRUCTURE DEVELOPMENT LTD, SEZ E-1, SHENDRA MIDC, FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154, MAHARASHTRA STATE
AURANGABAD

ÍNDIA

Manufacturing Lines:

1) Steriles: Aseptically Processed Small Volume Parenteral Solutions; Aseptically Processed Small Volume Parenteral Suspensions

Valid until: 10/16/2027

Published on the Brazilian Official Gazette – Resolution – RE n.º: 3.983, on: 10/13/2025

Requested by: GERAIS, COMÉRCIO E IMPORTAÇÃO DE MATERIAIS E EQUIPAMENTOS MEDICOS LTDA, **CNPJ:** 04.491.780/0001-70

Document electronically issued at: 10:28:29 on 10/14/2025 (Date/Brasilia Time Zone - UTC/GMT -3 hours)**Safety Control Code:** RPOS.VFNP.46BG.V35I.DYTL.XUEF.3UJR.1D6N.9EBW.Q911Check the authenticity on: http://www9.anvisa.gov.br/Peticionamento/validarcertificadoBPF_BPDA/

ЕВРАЗИЙСКИЙ ЭКОНОМИЧЕСКИЙ СОЮЗ

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ

СЕРТИФИКАТ

СООТВЕТСТВИЯ ПРОИЗВОДСТВА ЛЕКАРСТВЕННЫХ СРЕДСТВ ТРЕБОВАНИЯМ ПРАВИЛ
НАДЛЕЖАЩЕЙ ПРОИЗВОДСТВЕННОЙ ПРАКТИКИ ЕВРАЗИЙСКОГО ЭКОНОМИЧЕСКОГО СОЮЗА

№ GMP/EAEU/RU/02438-2025

Срок действия с 14.11.2025 по 13.11.2028

Выдан по итогам проведения фармацевтической инспекции в соответствии
с Правилами проведения фармацевтических инспекций, утвержденными
Решением Совета Евразийской экономической комиссии
от 3 ноября 2016 г. № 83

Министерство промышленности и торговли Российской Федерации
(Минпромторг России)

(полное и сокращенное наименования уполномоченного органа)

подтверждает следующее:

проведена фармацевтическая инспекция

Вокхард Лимитед

(полное наименование производителя)

710817-Вокхард Лимитед, Е-1/1, «Вокхард инфраструктура девелопмент ЛТД»,
Особая экономическая зона Е-1, Шендра МИДС, Промышленная зона «Файв
Стар», Шендра, Аурангабад 431154 Талука: Аурангабад зона 2,
район: Аурангабад зона 2, Индия

(адрес производственной площадки)

на основании заявления о выдаче сертификата соответствия производителя
(производителя нерезидента) лекарственных средств для медицинского
применения требованиям Правил надлежащей производственной практики
Евразийского экономического союза от 20.03.2025 № 8/23.

На основании сведений, полученных при проведении инспектирования,
последнее из которых было проведено 11.11.2025 - 14.11.2025, установлено, что
данное фармацевтическое производство соответствует требованиям Правил
надлежащей производственной практики Евразийского экономического союза,

Страница 1 из 8

000002738

эквивалентных Принципам и Руководству Европейского союза по надлежащей производственной практике лекарственных средств для медицинского и ветеринарного применения и принципам Системы сотрудничества фармацевтических инспекций (PIC/S).

Настоящий сертификат отражает статус производственной площадки на момент проведения фармацевтической инспекции и по истечении более 3 лет от даты последнего дня последнего инспектирования не может считаться документом, свидетельствующим о статусе соответствия. Срок действия сертификата может быть сокращен при использовании соответствующих принципов управления рисками при наличии соответствующей записи в поле «Ограничения или пояснительные заметки, касающиеся области применения настоящего сертификата».

Сертификат является действительным в случае представления всех его листов (как основных листов, так и дополнительных листов).

Аутентичность (подлинность) настоящего сертификата можно проверить в базе данных Минпромторга России.

Если сертификат не представлен в указанной базе данных, следует обратиться в уполномоченный орган, его выдавший.

Заместитель Министра

Е.Г. Приезжева



19 декабря 2025 г.
(дата выдачи сертификата)

**МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ**

GMP/EAEU/RU/02438-2025

☒ Лекарственные средства для медицинского применения	
☐ Лекарственные препараты для клинических исследований (испытаний)	
Код	Наименование
1. ПРОИЗВОДСТВЕННЫЕ ОПЕРАЦИИ – ЛЕКАРСТВЕННАЯ ПРОДУКЦИЯ	
1.1	Стерильная продукция
☒	1.1.1. Производимая в асептических условиях (операции обработки для следующих лекарственных форм):
	1.1.1.1. Жидкие лекарственные формы большого объема
☒	1.1.1.2. Жидкие лекарственные формы малого объема: раствор, суспензия
	1.1.1.3. Лиофилизаты
	1.1.1.4. Твердые лекарственные формы и имплантаты
	1.1.1.5. Мягкие лекарственные формы
	1.1.1.6. Прочая продукция, производимая в асептических условиях
☒	1.1.2. Подвергаемая финишной стерилизации (операции обработки для следующих лекарственных форм):
	1.1.2.1. Жидкие лекарственные формы большого объема
☒	1.1.2.2. Жидкие лекарственные формы малого объема: раствор
	1.1.2.3. Твердые лекарственные формы и имплантаты
	1.1.2.4. Мягкие лекарственные формы
	1.1.2.5. Прочая продукция, подвергаемая финишной стерилизации
☒	1.1.3. Выпускающий контроль качества (выпуск серии)
1.2	Нестерильная продукция
	1.2.1. Нестерильная продукция (технологические операции для получения следующих лекарственных форм):
	1.2.1.1. Капсулы в твердой оболочке
	1.2.1.2. Капсулы в мягкой оболочке
	1.2.1.3. Жевательные лекарственные формы
	1.2.1.4. Импрегнированные лекарственные формы
	1.2.1.5. Жидкие лекарственные формы для наружного применения
	1.2.1.6. Жидкие лекарственные формы для внутреннего применения
	1.2.1.7. Медицинские газы
	1.2.1.8. Прочие твердые лекарственные формы
	1.2.1.9. Препараты, находящиеся под давлением
	1.2.1.10. Радионуклидные генераторы

	1.2.1.11. Мягкие лекарственные формы
	1.2.1.12. Свечи (суппозитории)
	1.2.1.13. Таблетки
	1.2.1.14. Трансдермальные пластыри
	1.2.1.15. Прочая нестерильная продукция
	1.2.2. Выпускающий контроль качества (сертификация серии)
1.3	Биологическая лекарственная продукция
☒	1.3.1. Биологическая лекарственная продукция:
	1.3.1.1. Продукты крови
	1.3.1.2. Иммунобиологическая продукция
	1.3.1.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	1.3.1.4. Генотерапевтическая продукция
☒	1.3.1.5. Биотехнологическая продукция: прочая биотехнологическая продукция: раствор, суспензия
	1.3.1.6. Продукция, выделенная из животных источников или органов (тканей) человека
	1.3.1.7. Тканеинженерная продукция (продукция тканевой инженерии)
	1.3.1.8. Прочая биологическая лекарственная продукция
☒	1.3.2. Выпускающий контроль (сертификация серии) (перечень видов продукции):
	1.3.2.1. Продукты крови
	1.3.2.2. Иммунобиологическая продукция
	1.3.2.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	1.3.2.4. Генотерапевтическая продукция
☒	1.3.2.5. Биотехнологическая продукция
	1.3.2.6. Продукция, выделенная из животных источников или органов (тканей) человека

Заместитель Министра

Е.Г. Приезжева



19 декабря 2025 г.

(дата выдачи сертификата)

**МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ**

GMP/EAEU/RU/02438-2025

	1.3.2.7. Тканеинженерная продукция (продукция тканевой инженерии)
	1.3.2.8. Прочая биологическая лекарственная продукция
1.4	Прочая лекарственная продукция или производственная деятельность
☒	1.4.1. Производство:
	1.4.1.1. Растительная продукция
	1.4.1.2. Гомеопатическая продукция
☒	1.4.1.3. Прочая продукция: прочие группы лекарственных препаратов: раствор
☒	1.4.2. Стерилизация фармацевтических субстанций, вспомогательных веществ, готовой продукции:
☒	1.4.2.1. Фильтрация
	1.4.2.2. Сухожаровая стерилизация
☒	1.4.2.3. Стерилизация паром
	1.4.2.4. Химическая стерилизация
	1.4.2.5. Стерилизация гамма-излучением
	1.4.2.6. Стерилизация электронным излучением
	1.4.3. Прочее
1.5	Упаковка
	1.5.1. Первичная упаковка:
	1.5.1.1. Капсулы в твердой оболочке
	1.5.1.2. Капсулы в мягкой оболочке
	1.5.1.3. Жевательные лекарственные формы
	1.5.1.4. Импрегнированные лекарственные формы
	1.5.1.5. Жидкие лекарственные формы для наружного применения
	1.5.1.6. Жидкие лекарственные формы для внутреннего применения
	1.5.1.7. Медицинские газы
	1.5.1.8. Прочие твердые лекарственные формы
	1.5.1.9. Препараты, находящиеся под давлением
	1.5.1.10. Радионуклидные генераторы
	1.5.1.11. Мягкие лекарственные формы
	1.5.1.12. Свечи (суппозитории)
	1.5.1.13. Таблетки
	1.5.1.14. Трансдермальные пластыри

	1.5.1.15. Прочая нестерильная лекарственная продукция
☒	1.5.2. Вторичная упаковка
1.6	Контроль качества
☒	1.6.1. Микробиологические испытания: стерильность
	1.6.2. Микробиологические испытания: микробиологическая чистота
☒	1.6.3. Химические (физические) испытания
☒	1.6.4. Биологические испытания
2. ИМПОРТ ЛЕКАРСТВЕННОЙ ПРОДУКЦИИ	
2.1	Контроль качества импортируемой лекарственной продукции
	2.1.1. Микробиологические испытания: стерильность
	2.1.2. Микробиологические испытания: микробиологическая чистота
	2.1.3. Химические (физические) испытания
	2.1.4. Биологические испытания
2.2	Сертификация серии импортируемой лекарственной продукции
	2.2.1 Стерильная продукция:
	2.2.1.1. Производимая в асептических условиях
	2.2.1.2. Подвергаемая финишной стерилизации
	2.2.2. Нестерильная продукция
	2.2.3. Биологическая лекарственная продукция:
	2.2.3.1. Продукты крови
	2.2.3.2. Иммунобиологическая продукция
	2.2.3.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	2.2.3.4. Генотерапевтическая продукция
	2.2.3.5. Биотехнологическая продукция
	2.2.3.6. Продукция, выделенная из животных источников или органов (тканей) человека
	2.2.3.7. Тканеинженерная продукция (продукция тканевой инженерии)
	2.2.3.8. Прочая биологическая лекарственная продукция
2.3	Прочая деятельность по импорту (ввозу)

Заместитель Министра

Е.Г. Приезжева



19 декабря 2025 г.

(дата выдачи сертификата)

**МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ**

GMP/EAEU/RU/02438-2025

	2.3.1. Площадка физического импорта (ввоза)
	2.3.2. Импорт промежуточной продукции, подвергающейся дальнейшей обработке
	2.3.3. Прочее
3. ПРОИЗВОДСТВЕННЫЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ СУБСТАНЦИИ	
Фармацевтическая субстанция (субстанции):	
3.1	Производство фармацевтических субстанций методом химического синтеза
	3.1.1. Производство промежуточных продуктов фармацевтической субстанции
	3.1.2. Производство неочищенной фармацевтической субстанции
	3.1.3. Солеобразование (очистка): указать (например: перекристаллизация)
	3.1.4. Прочее
3.2	Производство фармацевтических субстанций методами выделения из природных источников
	3.2.1. Выделение фармацевтических субстанций из источников растительного происхождения
	3.2.2. Выделение фармацевтических субстанций из источников животного происхождения
	3.2.3. Выделение фармацевтических субстанций из органов (тканей) человека
	3.2.4. Выделение фармацевтических субстанций из источников минерального происхождения
	3.2.5. Модификация выделенной фармацевтической субстанции
	3.2.6. Очистка выделенной фармацевтической субстанции
	3.2.7. Прочее
3.3	Производство фармацевтических субстанций с использованием биологических процессов
	3.3.1. Ферментация
	3.3.2. Производство с использованием клеточных культур
	3.3.3. Выделение (очистка)
	3.3.4. Модификация
	3.3.5. Прочее

3.4	Производство стерильных фармацевтических субстанций
	3.4.1. Фармацевтические субстанции, производимые в асептических условиях
	3.4.2. Фармацевтические субстанции, подвергаемые финишной стерилизации
3.5	Завершающие стадии производства фармацевтических субстанций
	3.5.1. Стадии физической обработки
	3.5.2. Первичная упаковка
	3.5.3. Вторичная упаковка
	3.5.4. Прочее
3.6	Контроль качества
	3.6.1. Физические (химические) испытания
	3.6.2. Микробиологические испытания (включая испытание на стерильность)
	3.6.3. Микробиологические испытания (исключая испытание на стерильность)
	3.6.4. Биологические испытания
4. ПРОЧИЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ СУБСТАНЦИИ	
Ограничения или пояснительные заметки, касающиеся области применения сертификата: –	

Заместитель Министра



19 декабря 2025 г.

(дата выдачи сертификата)

Е.Г. Приезжева

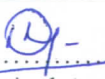


NATIONAL MEDICINES REGULATORY AUTHORITY
SRI LANKA.

120, Norris Canal Road, Colombo 10, Sri Lanka.
Telephone: +94 011 2698896/7 Fax: +94 011 2689704

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EVALUATION REPORT ON OVERSEAS PHARMACEUTICAL MANUFACTURING FACILITY

Application No	NMRA/MP/701		
Name of the Manufacturer	Wockhardt Limited,		
Site Address	E-1, Wockhardt Infrastructure Development Ltd, SEZ E -1, Shendra MIDC, Five Star Industrial Area, Shendra Aurangabad -431154, India		
Address, Head Office	Wockhardt Tower, Bandra Kurla Complex, Mumbai-400051, India		
Local Agent	Emerchemie NB (Ceylon) Limited, No.60, Maligawatte Road, Colombo 10		
Categories of Products and dosage forms	Bio therapeutic products, Aseptically prepared small volume parenteral solution Aseptically prepared small volume parenteral suspension		
Evaluator's Comments:	Manufacturing site has been inspected by two PIC/s members such as Brazilian Health Regulatory Agency (ANVISA) and Thailand Health Regulatory Authority. Based on the GMP approval granted by above reference Authority site can be considered for the approval excluding GMP inspection by NMRA, only for Human Insulin which are originated from rDNA.		
Recommendation	Recommended to approve based on the GMP report issued by PIC/s Member country		
Evaluated by	 Pharmaceutical Assessor (PA7)	Date of evaluation	09/12/2024
Recommendation of CP evaluation committee	Recommended for approval. 1.  PA1 2.  AAF 3.  PA14		
Final decision:	The site is <u>approved</u> conditionally approved/ not approved/ decision awaiting  CEO National Medicines Regulatory Authority		

31 DEC 2024



Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-29 Jul 2023

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/AD/126891/2023/11/46496**

On the basis of the inspection carried out on **13/06/2023 & 14/06/2023**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

- Name of the Firm : **WOCKHARDT LIMITED**
Address : **E-1/1, WOCKHARDT INFRASTRUCTURE DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC, FIVE STAR INDUSTRIAL AREA, SHENDRA AURANGABAD 431154 MAHARASHTRA STATE, INDIA**
- Licence No. : **AD091 In Form 25, AD063 In Form 28, AD007 In Form 28D**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	External Preparation (Ointments / Creams / Lotion/Gel)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Injectables	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Injectables	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Liquid Orals	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

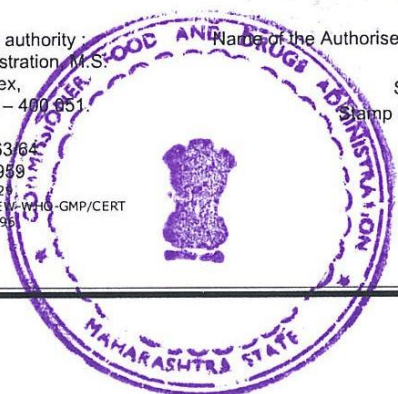
This certificate remains valid until 28 Jul 2026 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051,
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94512689120230725
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : **MR BHUSHAN PATIL, J.C**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:29 Jul 2023



Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record “not applicable” in cases where there is no legal framework for the issuing of a licence.
4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

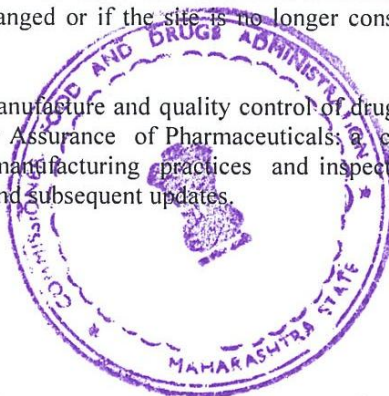
Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s) ¹	Category (ies)	Activity (ies)
Starting material (s) ²		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals, a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026 /46496

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
1	Adenosine 3mg/ml Solution for Injection	Each Vial contains Adenosine Ph.Eur 6.00 mg/2ml Sodium Chloride Ph.Eur 0.9 % Water for Injection Ph.Eur qs Pack : 2 mL Vial For rapid intravenous injection only For Single use only
2	Biphasic Isophane Insulin Injection IP 100 IU/mL (30/70) (Recombinant DNA origin) Monocomponent Insulin Human	Each ml contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Penfill
3	Biphasic Isophane Insulin Injection IP 100 IU/mL (50/50) (Recombinant DNA origin) Monocomponent Insulin Human	Each ml contains: Human Insulin IP 100 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Penfill
4	Biphasic Isophane Insulin Injection IP 200 IU/mL (30/70) (Recombinant DNA origin) Monocomponent Insulin Human	Each Dispopen contains: Each mL contains: Human Insulin IP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Dispopen containing 3 mL Cartridge
5	Biphasic Isophane Insulin Injection IP 200 IU/mL (30/70) (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 3 mL Cartridge
6	Insulin Glargine Injection IP 100 IU/mL (Recombinant DNA origin)	Each Dispopen contains one 3 mL cartridge of Insulin Glargine Injection IP 100 IU/mL: Each mL contains: Insulin Glargine IP 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injections IP qs Pack: Dispopen containing 3 mL Cartridge




Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

7	Insulin Glargine Injection IP 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine IP 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injections IP qs Pack: 3 mL Cartridge
8	Insulin Injection IP 100 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each ml contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection IP qs Pack: Penfill

1 2 3 4 5 6 7 8 9

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : MR BRUSHAN PATIL , J.C

Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:29 Jul 2023



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026 /46496

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC, FIVE STAR INDUSTRIAL AREA, SHENDRA AURANGABAD 431154 MAHARASHTRA STATE, INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

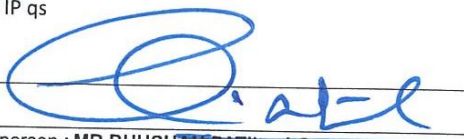
Sr.No.	Name of the Product	Composition
9	Insulin Injection IP 200 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each Dispopen contains: One 3 mL Cartridge of Insulin Injection IP 200 IU/mL Each mL contains: Human Insulin IP 200 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injections IP qs Pack: Dispopen containing 3 mL Cartridge
10	Insulin Injection IP 200 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each ml contains: Human Insulin IP 200 IU m-Cresol ((as preservative) USP 0.25 % w/v (as preservative) Water for Injections IP qs Pack: 3mL Cartridge
11	Isophane Insulin Injection IP 100 IU/mL (Recombinant DNA origin) NPH – Monocomponent Insulin Human	Each ml of Isophane suspension contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Penfill
12	Aqueous Cream BP	Contains: Emulsifying Ointment 30 % w/w (The ingredients of which are Cetostearyl Alcohol, Sodium Lauryl Sulphate, Liquid Paraffin (Light) and white soft paraffin) Phenoxyethanol 1 % w/w and Purified water to 100 % w/w
13	Biphasic Isophane Insulin Injection IP 100 IU/mL (30/70) (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 3mL Cartridge
14	Biphasic Isophane Insulin Injection IP 100 IU/mL (30/70) (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 mL Vial
15	Biphasic Isophane Insulin Injection IP 100 IU/mL (50/50) (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 3 mL Cartridge



(Signature)
Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

16 Biphasic Isophane Insulin Injection
IP 40 IU/mL (30/70)
(Recombinant DNA origin)
Monocomponent Insulin Human

Each mL contains:
Human Insulin IP 40 IU
(30% Soluble Insulin Injection & 70% Isophane Insulin Injection)
m-Cresol (as preservative) USP 0.16 % w/v
Phenol (as preservative) IP 0.065 % w/v
Water for Injections IP qs
Pack: 10 mL Vial



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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94512689120230729
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : MR BHUSHAN PATIL, J.C

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 29 Jul 2023



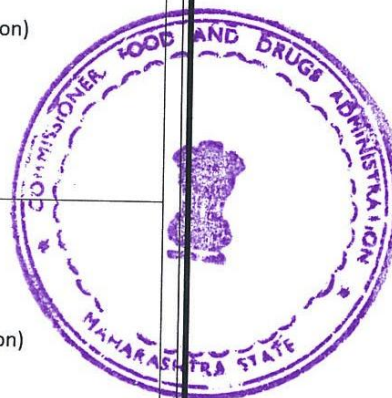
LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026
/46496

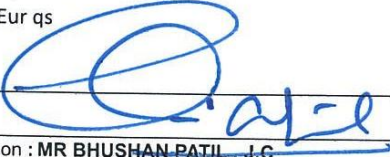
Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
17	Biphasic Isophane Insulin Injection IP 40 IU/mL (50/50) (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 40 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 mL Vial
18	Cetirizine 5 mg/5 ml Oral Solution	Each 5 ml Contain: Cetirizine Hydrochloride 5 mg
19	Consegna 30/70 200 IU/mL Biphasic Isophane Insulin Injection BP 200 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
20	Consegna 30/70 200 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 200 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
21	Consegna 30/70 Dispopen 200 IU/mL Biphasic Isophane Insulin Injection BP 200 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each Dispopen contains: one 3 ml cartridge of Biphasic Isophane Insulin Injection BP 200 IU/mL Each mL contains: Insulin Human USP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge
22	Consegna R 200 IU/mL Insulin Human Injection USP 200 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 200 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
23	Consegna R Dispopen 200 IU/mL Insulin Human Injection USP 200 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each Dispopen contains One 3 mL cartridge of Insulin Human Injection USP 200 IU/mL Each mL contains: Insulin Human USP 200 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge



(Signature)
**Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai**

24	Glaritus 100 IU/mL Insulin Glargine Injection BP 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine Ph.Eur 100 IU m-Cresol (as preservative) Ph.Eur 0.27 % w/v Water for Injections Ph.Eur qs Pack: 3 mL Cartridge
		
1 2 3 4 5 6 7 8 9		
Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai – 400 051. Maharashtra, INDIA. Tel: +91-22-26592363/64 Fax: +91-22-26591959 1COW94512689120230729 WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/126891/2023/11/46496		Name of the Authorised person : MR BHUSHAN PATIL, J.C Signature : Stamp and Date : Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S. Bandra (E), Mumbai. Maharashtra State, India Date: 29 Jul 2023



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026 /46496

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
25	Glaritus 100 IU/mL Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA origin)	Each mL contains : Insulin Glargine USP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injection USP qs Pack: 3 mL cartridge
26	Glaritus 100 IU/mL Recombinant Insulin Glargine Injection 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
27	Glaritus Dispopen Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA origin)	Each Dispopen contains one 3 mL Cartridge of Insulin Glargine Injection USP 100 IU/mL Each mL contains Insulin Glargine USP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injection USP qs Pack : Dispopen containing 3 mL Cartridge
28	Glaritus Dispopen 100 IU/mL Insulin Glargine Injection BP 100 IU/mL (Recombinant DNA origin)	Each Dispopen contains one 3 mL cartridge of Insulin Glargine Injection BP 100 IU/mL: Each mL contains: Insulin Glargine Ph.Eur 100 IU m-Cresol (as preservative) Ph.Eur 0.27 % w/v Water for Injections Ph.Eur qs Pack: Dispopen containing 3 mL Cartridge
29	Glaritus Dispopen 100 IU/mL Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA origin)	Each Dispopen contains one 3 mL cartridge of Insulin Glargine Injection USP 100 IU/mL: Each mL contains: Insulin Glargine USP 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge
30	Insulin Injection IP 100 IU/mL (Recombinant DNA origin) Regular (Soluble/Neutral) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injections IP qs Pack: 3 mL Cartridge
31	Insulin Injection IP 100 IU/mL (Recombinant DNA origin) Regular (Soluble/Neutral) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injections IP qs Pack: 10 mL Vial
32	Insulin Injection IP 40 IU/mL (Recombinant DNA origin) Regular (Soluble/Neutral) Monocomponent Insulin Human	Each mL contains: Human Insulin IP 40 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injections IP qs Pack: 10 mL Vial

1 2 3 4 5 6 7 8 9

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94512689120230729
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : MR BHUSHAN PATIL , J.C

Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
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E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
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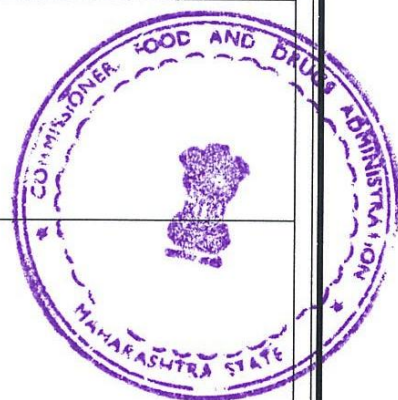
Sr.No.	Name of the Product	Composition
33	Isophane Insulin Injection IP 100 IU/mL (Recombinant DNA origin), NPH-Monocomponent Insulin Human	Each mL of Isophane Suspension contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 3 mL Cartridge
34	Isophane Insulin Injection IP 100 IU/mL (Recombinant DNA origin), NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 mL Vial
35	Isophane Insulin Injection IP 40 IU/mL (Recombinant DNA origin), NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Human Insulin IP 40 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 mL Vial
36	Omeprazole Delayed Release Capsules USP 20 mg	Each Delayed Release Capsule Contains: Omeprazole USP 20 mg
37	Venlafaxine Hydrochloride Extended Release Tablets 150 mg	Each Extended Release Tablet Contains: Venlafaxine Hydrochloride equivalent to 150 mg of Venlafaxine
38	Venlafaxine Hydrochloride Extended Release Tablets 225 mg	Each Extended Release Tablet Contains: Venlafaxine Hydrochloride equivalent to 225 mg of Venlafaxine
39	Venlafaxine Hydrochloride Extended Release Tablets 37.5 mg	Each Extended Release Tablet Contains: Venlafaxine Hydrochloride equivalent to 37.5 mg of Venlafaxine
40	Venlafaxine Hydrochloride Extended Release Tablets 75 mg	Each Extended Release Tablet Contains: Venlafaxine Hydrochloride equivalent to 75 mg of Venlafaxine

1 2 3 4 5 6 7 8 9

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94512689120230729
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : **MR BHUSHAN PATIL, J.C**

Signature :
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:29 Jul 2023



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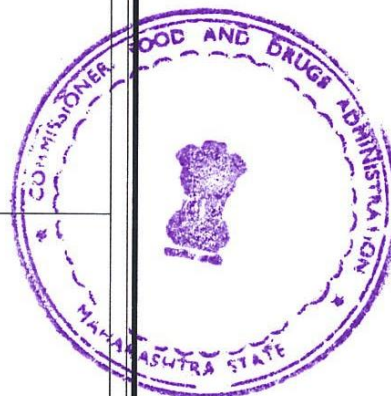
LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026 /46496

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
41	Wosulin 30/70 100 IU/mL Biphasic Isophane Insulin Injection BP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains Insulin Human USP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
42	Wosulin 30/70 100 IU/mL Biphasic Isophane Insulin Injection BP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial
43	Wosulin 30/70 100 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
44	Wosulin 30/70 100 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial
45	Wosulin 30/70 200 IU/mL Biphasic Isophane Insulin Injection BP 200 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
46	Wosulin 30/70 200 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 200 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
47	Wosulin 30/70 40 IU/mL Biphasic Isophane Insulin Injection BP 40 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 40 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial



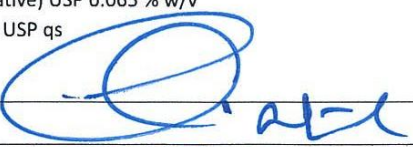
Joint Commissioner (H.Q.)
 Food and Drugs Administration
 Maharashtra State, Mumbai

48	Wosulin 30/70 40 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 40 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 40 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial
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1 2 3 4 5 6 7 8 9

Address of certifying authority :
 Food & Drug Administration, M.S.
 Bandra-kurla Complex,
 Bandra (E), Mumbai – 400 051.
 Maharashtra, INDIA.
 Tel: +91-22-26592363/64
 Fax: +91-22-26591959
 1COW94512689120230729
 WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
 /AD/126891/2023/11/46496

Name of the Authorised person : **MR BHUSHAN PATIL, J.C**

Signature : 

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 29 Jul 2023



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026 /46496

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
49	Wosulin 30/70 Dispopen 100 IU/mL Biphaseic Isophane Insulin Injection BP 100IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each dispopen contains one 3 mL cartridge of Biphaseic Isophane Insulin Injection BP, 100 IU/mL Each mL contains: Insulin Human USP 100 IU (30% soluble insulin injection and 70% isophane insulin injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge
50	Wosulin 30/70 Dispopen 200 IU/mL Biphaseic Isophane Insulin Injection BP 200 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each Dispopen contains One 3mL Cartridge of Biphaseic Isophane Insulin Injection BP 200 IU/mL Each mL contains: Insulin Human USP 200 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge
51	Wosulin 50/50 Dispopen 100 IU/mL Biphaseic Isophane Insulin Injection BP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each dispopen contains one 3mL cartridge of Biphaseic Isophane Insulin Injection BP...100IU/mL Each mL contains: Insulin Human USP 100 IU (50% soluble insulin injection and 50% isophane insulin injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3mL Cartridge
52	Wosulin 50/50 100 IU/mL Biphaseic Isophane Insulin Injection BP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3mL Cartridge
53	Wosulin 50/50 100 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
54	Wosulin 50/50 40 IU/mL Human Insulin Isophane Suspension and Human Insulin Injection USP 40 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 40 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial
55	Wosulin 50/50 40 IU/mL Biphaseic Isophane Insulin Injection BP 40 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 40 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial



(Signature)
Joint Commissioner (H.O.)
Food and Drugs Administration,
Maharashtra State, Mumbai

56	Wosulin N 100 IU/mL Isophane Insulin Human Suspension USP 100 IU/mL (Recombinant DNA origin) NPH-Monocomponent Insulin Human	Each ml of Isophane suspension contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial
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1 2 3 4 5 6 7 8 9

Address of certifying authority :
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Bandra-kurla Complex,
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Tel: +91-22-26592363/64
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Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 29 Jul 2023



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026
/46496

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
57	Wosulin N 100 IU/mL Isophane Insulin Human Suspension USP 100 IU/mL (Recombinant DNA origin) NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
58	Wosulin N 40 IU/mL Isophane Insulin Human Suspension USP 40 IU/mL (Recombinant DNA origin) NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Insulin Human USP 40 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 mL Vial
59	Wosulin N Dispopen 100 IU/mL Isophane Insulin Human Suspension USP 100 IU/mL (Recombinant DNA origin) NPH-Monocomponent Insulin Human	Each Dispopen contains one 3 mL cartridge of Isophane Insulin Human Suspension USP 100 IU/mL Each mL contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge
60	Wosulin R 100 IU/mL Insulin Human Injection USP 100 IU/mL (Recombinant DNA origin), Regular (Soluble / Neutral), Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: 10 mL Vial
61	Wosulin R 100 IU/mL Insulin Human Injection USP 100 IU/mL (Recombinant DNA origin), Regular (Soluble / Neutral), Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
62	Wosulin R 200 IU/mL Insulin Human Injection USP 200 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each mL contains Insulin Human USP 200 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: 3 mL Cartridge
63	Wosulin R 40 IU/mL Insulin Human Injection USP 40 IU/mL (Recombinant DNA origin), Regular (Soluble / Neutral), Monocomponent Insulin Human	Each mL contains: Insulin Human USP 40 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: 10 mL Vial
64	Wosulin R Dispopen 100 IU/mL Insulin Human Injection USP 100 IU/mL (Recombinant DNA origin) Regular (soluble/neutral) Monocomponent Insulin Human	Each Dispopen contains one 3 mL cartridge of Insulin Human Injection USP 100IU/mL Each mL contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge



1 2 3 4 5 6 7 8 9

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
ICOW94512689120230729
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : MR BHUSHAN PATIL, J.C

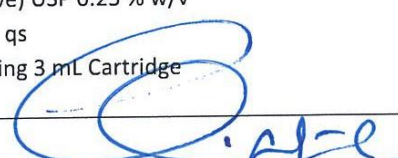
Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:29 Jul 2023

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/AD/126891/2023/11 VALID UP TO :28 Jul 2026
/46496
Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
AURANGABAD 431154 MAHARASHTRA STATE,
INDIA
Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
65	Wosulin R Dispopen 200 IU/mL Insulin Human Injection USP 200 IU/mL (Recombinant DNA origin) Regular (Soluble / Neutral) Monocomponent Insulin Human	Each Dispopen contains One 3 mL cartridge of Insulin Human Injection USP 200 IU/mL Each mL contains: Insulin Human USP 200 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge

1 2 3 4 5 6 7 8 9



Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94512689120230729
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/126891/2023/11/46496

Name of the Authorised person : MR BHUSHAN PATIL , J.C

Signature :
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:29 Jul 2023





Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-25 Jun 2024

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/AD/132492/2024/11/50640**

On the basis of the inspection carried out on **06/02/2024 & 07/02/2024**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **WOCKHARDT LIMITED**
Address : **E-1/1, WOCKHARDT INFRASTRUCTURE DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC, FIVE STAR INDUSTRIAL AREA, SHENDRA CHHATRAPATI SAMBAJINAGAR 431154 MAHARASHTRA STATE, INDIA**
2. Licence No. : **AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Liquid Injections / Infusions (LVP)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 24 Jun 2027 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94513249220240625
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/132492/2024/11/50640

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**

**Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:25 Jun 2024**



Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

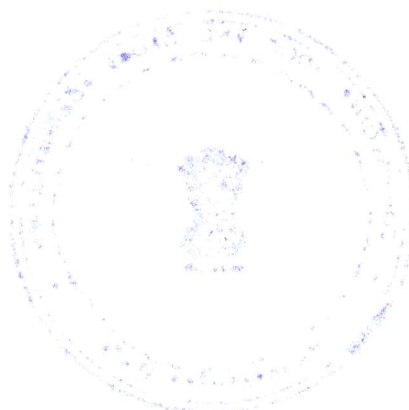
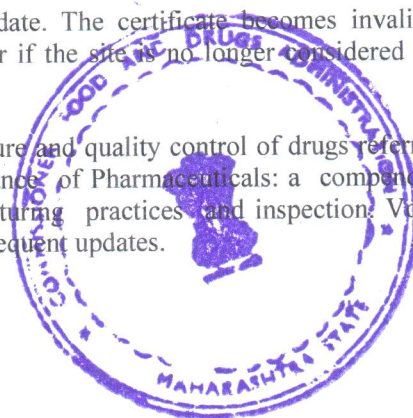
Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-
GMP/CERT/AD/132492/2024/11/50640 **VALID UP TO :24 Jun 2027**

Name of Manufacturing Firm : WOCKHARDT LIMITED
E-1/1, WOCKHARDT INFRASTRUCTURE
DEVELOPMENT LTD., SEZ E-1, SHENDRA MIDC,
FIVE STAR INDUSTRIAL AREA, SHENDRA
CHHATRAPATI SAMBHAJINAGAR 431154
MAHARASHTRA STATE, INDIA

Drug License No : AD091 In Form 25,
AD063 In Form 28,
AD007 In Form 28D

Sr.No.	Name of the Product	Composition
1	Levonadifloxacin Injection (I.V.) 800mg/100ml	Each 100 ml contains : Levonadifloxacin L-Arginine Tetrahydrate equivalent to Levonadifloxacin 800mg L-Arginine IP qs Sodium Chloride IP qs Water for Injection IP qs Intravenous Injection (Single use) 100 mL Infusion Bottle
2	PARACETAMOL INFUSION IP 10 mg/ml	Each ml contains: Paracetamol IP 10 mg Water for Injections IP qs Pack: 100 ml single dose vial

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW94513249220240625
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/132492/2024/11/50640

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:25 Jun 2024



GMP Certificates

MINISTRY OF HEALTH
BRAZILIAN HEALTH REGULATORY AGENCY

GOOD MANUFACTURING PRACTICES CERTIFICATE

The Brazilian Health Regulatory Agency (ANVISA), under its duties, certifies the company indicated below is periodically Inspected and monitored by the National Health Surveillance System and complies with the Good Manufacturing Practices guidelines given by Brazilian legislation, which is in accordance with the recommendations of the World Health Organization.

WOCKHARDT LIMITED

BIOTECH PARK, H-14/2, M.I.D.C. WALUJ, CHHATRAPATI SAMBHAJINAGAR 431136, MAHARASHTRA STATE

CHHTRAPATI SAMBHAJINAGAR

ÍNDIA

Manufacturing Lines:

1) Steriles: Aseptically Processed Small Volume Parenteral Solutions

Valid until: 04/10/2027

Published on the Brazilian Official Gazette – Resolution – RE n.º: 998, on: 03/16/2026

Requested by: FARMA VISION IMPORTAÇÃO E EXPORTAÇÃO DE MEDICAMENTOS LTDA, **CNPJ**: 09.058.502/0001-48

Document electronically issued at: 09:58:12 on 03/16/2026 (Date/Brasilia Time Zone - UTC/GMT -3 hours)

Safety Control Code: 87ST.UAOX.HVQI.PFNC.YYDA.WS6E.881N.GX2C.96JJ.WIT0

Check the authenticity on: http://www9.anvisa.gov.br/Peticionamento/validarcertificadoBPF_BPDA/

308439



**CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE
GUIDELINES**

THE NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

*Issued under Regulation 19(5) of the National Drug Policy and Authority (Licensing) Regulations,
2014*

Certificate No. 100/GMP/2022

This is to certify that the drug manufacturing facility:

Name of facility: Wockhardt Limited.

Physical address of facility: E-1/1 Wockhardt Infrastructure Development Special
Economic Zone E-1 Shendra MIDC Five-star
Industrial Area, Shendra, Aurangabad – 431201, India.

License number of the manufacturer: AD/007 in form 28 D, Issued by Food and Drug
Administration of Maharashtra
Valid until 03/03/2023.

Has been inspected by the Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the inspection carried out on **11th and 12th April 2022**, it is certified that the facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table 1 below.

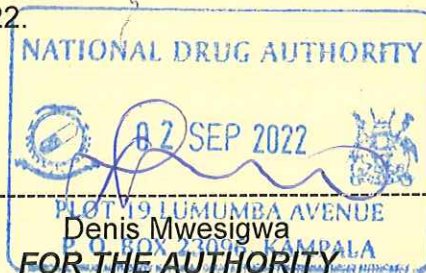
Table 1: Approved lines

No.	Dosage form	Category	Activities
1.	Aseptically filled Small Volume Liquids in vials and cartridges (Insulin)	Biologicals	Manufacture of Finished Pharmaceutical (medicinal) Product
2.	Terminally sterilized Small Volume Liquids in vials	Non-Beta Lactam	
3.	Lyophilizates		

The responsibility for the quality of the individual batches of the drugs manufactured through this process lies with the manufacturer.

This certificate remains valid **12th April 2025**. It becomes invalid if the activities or the categories certified change or if the facility is no longer considered to be in compliance with GMP.

Issue Date: 02nd September 2022.





T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

İYİ ÜRETİM UYGULAMALARI (GMP) SERTİFİKASI

Sertifika No: 2024-200/1	Sertifika Tarihi: 23.05.2024
Ürün Adı/Adları:	Glaritus 100 IU/mL SC Kullanım İçin Enjeksiyonluk Çözelti İçeren Kartuş (3 mL)
Etkin Madde/Maddeler:	İnsulin glarjin
İthalatçı Firma Adı:	Onko İlaç San. ve Tic. A.Ş.
Üretim Tesisi Adı:	Wockhardt Limited
Üretim Tesisi Adresi:	Biotech Park H-14/2 MIDC, Waluj Aurangabad 431136 Maharashtra State, Hindistan
Üretim Tesisinde Gerçekleştirilen Faaliyetler:	Bulk üretim, Primer ambalajlama, Sekonder ambalajlama, Seri serbest bırakma
Denetim Tarihi:	08-11.08.2023

05.10.2023 tarihli ve E-24931227-000-15235 sayılı Makam Oluru ile yürürlüğe giren "Yurt Dışı Üretim Tesislerinin GMP Denetimleri İçin Yapılacak Müracaatlara Dair Kılavuz"un A bendi (yerinde denetim) kapsamında yukarıda adı geçen ürünün bahsi geçen tesiste belirtilen işlem basamaklarının "İyi Üretim Uygulamaları (GMP)" kuralları doğrultusunda yapıldığına dair sertifikadır.

Dr. Asım HOCAOĞLU
Kurum Başkanı



Not: Bu belge 11.08.2026 tarihine kadar ve söz konusu ürünün/ürünlerin varsa ilgili kılavuz çerçevesince denetimi gerekli diğer üretim aşamalarının gerçekleştirildiği tesisler için düzenlenmiş olan GMP belgeleri ile birlikte geçerlidir.

Bu belge
güvenli
elektronik
imza ile
imzalanmıştır.

Belge
Takip
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turkiye.go
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MINISTRY of HEALTH of the REPUBLIC of TURKEY
TURKISH MEDICINES AND MEDICAL DEVICES AGENCY
CERTIFICATE of GOOD MANUFACTURING PRACTICE

Certificate Number: 2024-200/1	Date of certificate: 23.05.2024
Product Name(s):	Glaritus 100 units/ml solution for injection in a cartridge (3mL)
Active ingredient(s):	Insulin glargine
Name of the exporter company:	Onko İlaç San. Ve Tic. A.Ş.
Name of the Manufacturing facility	Wockhardt Limited
Adress of the Manufacturing facility	Biotech Park H-14/2 MIDC, Waluj Aurangabad 431136 Maharashtra State, India
Activities performed at the manufacturing facility:	Bulk production, primary packaging, secondary packaging, batch release process
Inspection date:	08-11.08.2023

Within the scope of subparagraph A (on-site inspection) of the “Guideline on the Applications to be Made for GMP Audits of Foreign Production Facilities”, which entered into force with the Authority Approval dated 05.10.2023 and numbered E-24931227-000-15235, it is the certificate that the process steps of the above-mentioned product in the mentioned facility are carried out in accordance with the “Good Manufacturing Practices (GMP)” rules.

Dr. Asım HOCAOĞLU
Head of the instution

Note: This document is valid until 11.08.2026 and together with the GMP certificates issued for the facilities where other production stages of the product(s) in question are carried out, if any, for which inspection is required under the relevant guidelines.

274590



CERTIFICATE OF COMPLIANCE WITH GOOD MANUFACTURING PRACTICE GUIDELINES

THE NATIONAL DRUG POLICY AND AUTHORITY ACT, CAP 206

Issued under Regulation 19(5) of the National Drug Policy and Authority (Licensing) Regulations, 2014

Certificate No. 112/GMP/2023

This is to certify that the drug manufacturing facility:

Name of facility: Wockhardt Biotech Park Limited.

Physical address of facility: Biotech Park, H-14/2, MIDC., Waluj, Aurangabad-431136
Maharashtra - India.

License number of the manufacturer: Form 28D –AD/004 State and Drugs
Administration Aurangabad Division MH State
India. Valid up to up to 07/04/2023.

Has been inspected by the Authority for compliance with the Good Manufacturing Practice Guidelines.

On the basis of the inspection carried out on **17th and 18th October 2022**, it is certified that the facility indicated on this certificate complies with Good Manufacturing Practice for dosage forms listed in Table 1 below.

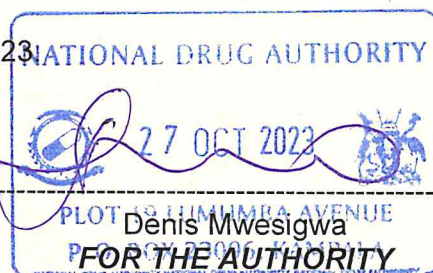
Table 1: Approved lines

No.	Dosage form	Category	Activities
1.	Aseptically filled Small Volume Parenteral Liquids (packed in vials)	Biologicals (Non-Beta Lactam)	Manufacture of Finished Pharmaceutical (medicinal) Product
2.	Aseptically filled Small Volume Parenteral Liquids (packed in cartridges)		
3.	Aseptically filled Small Volume Parenteral Liquids (packed in Pre-filled syringes).		

The responsibility for the quality of the individual batches of the drugs manufactured through this process lies with the manufacturer.

This certificate remains valid until **18th October 2025**. It becomes invalid if the activities or the categories certified change or if the facility is no longer considered to be in compliance with GMP.

Issue Date: 27th October 2023



PERSETUJUAN IZIN EDAR

T-RG.01.03.32.322.02.26.42997/NE

Sesuai dengan Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat, sebagaimana telah beberapa kali diubah terakhir dengan Peraturan Badan Pengawas Obat dan Makanan Nomor 23 Tahun 2025 tentang Perubahan Kelima atas Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat, dengan ini diberikan persetujuan Pendaftaran Obat di bawah ini:

Nama Obat : **GLARITUS**
Zat Aktif : Tiap ml mengandung:
- Insulin glargine 100 iu
Bentuk Sediaan : Injeksi
Kemasan : Dus, 5 dispopen + cartridge @ 3 ml
Nama Produsen : WOCKHARDT LIMITED, AURANGABAD, INDIA
Golongan Obat : Obat Keras
Dengan Nomor Izin Edar :

DKI2158300143A1

Kepada Industri Farmasi Pendaftar : PT. INFION, PASURUAN
dengan ketentuan :

1. Informasi Produk dan/atau Label yang diedarkan harus sesuai dengan rancangan terlampir.
2. Formulir Registrasi, Informasi Produk dan/atau Label terlampir merupakan bagian yang tidak terpisahkan dari Persetujuan Izin Edar ini.
3. Apabila di kemudian hari ada pihak lain yang lebih berhak atas Nama Obat sesuai dengan ketentuan peraturan perundang-undangan, Pendaftar harus mengganti Nama Obat tersebut di atas.
4. Wajib mencantumkan nama generik sesuai dengan ketentuan peraturan perundang-undangan.
5. Wajib mencantumkan Harga Eceran Tertinggi sampai pada kemasan terkecil.
6. PT. Infion bertanggung jawab penuh terhadap khasiat, keamanan dan mutu Obat yang diedarkan.
7. Persetujuan ini dapat dibekukan dan/atau dicabut sesuai dengan ketentuan Pasal 63 Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat.
8. Persetujuan Izin Edar DKI2158300143A1 yang dikeluarkan tanggal 01 April 2021 untuk Obat Glaritus, injeksi 100 iu/mL (dus, 5 dispopen + cartridge @ 3 mL) tidak berlaku lagi dan harus dikembalikan ke Badan Pengawas Obat dan Makanan.

Dikeluarkan : di JAKARTA
Tanggal : 12 Februari 2026
Masa Berlaku : 12 Februari 2031
a.n. Kepala Badan Pengawas Obat dan Makanan
Deputi Bidang Pengawasan Obat, Narkotika,
Psikotropika, Prekursor, dan Zat Adiktif



dr. William Adi Teja, MD., BMed., MMed



Nomor : B-PW.01.04.33.332.10.20.700

Jakarta, 7 Oktober 2020

Lampiran : -

Perihal : Fasilitas Pembuatan Obat Impor Glaritus
(Wockhardt Limited, India) Memenuhi Persyaratan CPOB

Yth. Pimpinan dan Apoteker Penanggung Jawab

PT Infion

Puri Mansion Cluster Rukan A 37

Jl. Lingkar Luar Barat, Kembangan Selatan

Jakarta Barat 11610

Sehubungan dengan surat Saudara No. 094/INF-REG/VIII/20 tanggal 26 Agustus 2020 perihal Permohonan Penilaian Dokumen Pra Inspeksi Fasilitas Wockhardt Limited, yang disampaikan dalam rangka registrasi obat impor berikut:

Nama Obat Jadi : Glaritus
Nama Zat Aktif : Insulin Glargine 100 IU/mL
Bentuk Sediaan : Injeksi
Pendaftar : PT Infion
Nama Produsen : Wockhardt Limited, India
Alamat : Biotech Park, H-14/2, M.I.D.C, Waluj, Aurangabad, Maharashtra – 431 136,
Produsen : India

dengan ini kami beritahukan bahwa berdasarkan hasil *desktop inspection*, fasilitas produksi Wockhardt Limited, India dinyatakan memenuhi persyaratan CPOB sehingga **proses registrasi obat impor Glaritus dari Wockhardt Limited, India dapat dilanjutkan.**

Demikian kami sampaikan.

Direktur Pengawasan Produksi Obat,
Narkotika, Psikotropika dan Prekursor



Dra. Nurma Hidayati, Apt., M.Epid.

Tembusan Yth.:

1. Deputi Bidang Pengawasan Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
2. Direktur Registrasi Obat



Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-11 Aug 2025

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/AD/150740/2025/11/56427**

On the basis of the inspection carried out on **03/07/2024 & 04/07/2025**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **WOCKHARDT LIMITED**
Address : **BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA**
2. Licence No. : **AD004 In Form 28D**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Injectables	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Injectables	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 10 Aug 2028 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

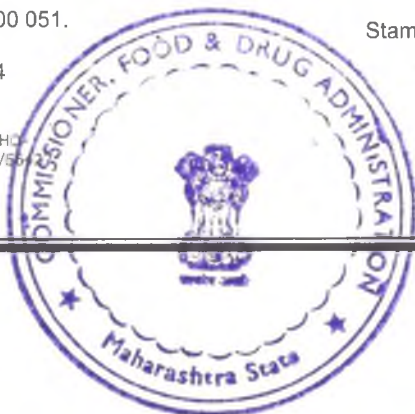
Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**

**Food & Drug Administration, M.S.
Bandra (E), Mumbai . .
Maharashtra State, India
Date:11 Aug 2025**



Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example - 1

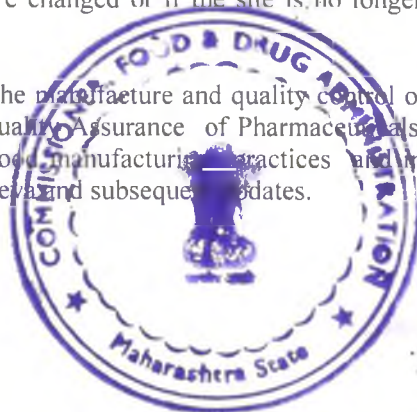
Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

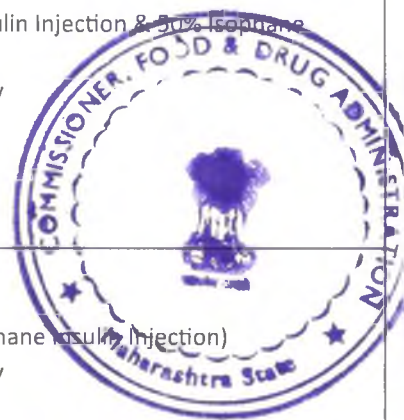
5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection. Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- VALID UP TO :10 Aug 2028
 GMP/CERT/AD/150740/2025/11/56427
 Name of Manufacturing Firm : WOCKHARDT LIMITED
 BIOTECH PARK, H-14/2, MIDC WALUJ
 CHHATRAPATI SAMBHAJINAGAR 431136
 MAHARASHTRA STATE, INDIA
 Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
1	Biphasic Isophane Insulin Injection IP (Recombinant DNA origin) (30% Regular Insulin Human neutral & 70% Isophane Insulin) 100 IU/mL, (30/70) Monocomponent Insulin (HUMAN).	Each mL contains: Human Insulin IP 100 IU (30% soluble Insulin injection & 70% Isophane Insulin injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 3 ml Cartridge.
2	Biphasic Isophane Insulin Injection IP (Recombinant DNA origin) (50% Regular Insulin Human neutral & 50% Isophane Insulin) 100 IU/mL, (50/50) Monocomponent Insulin (HUMAN)	Each mL contains: Human Insulin IP 100 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 3 mL Cartridge.
3	Biphasic Isophane Insulin Injection IP (Recombinant DNA origin) Monocomponent Insulin (Human) 100 IU/mL (30/70)	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 1.5 ml & 3 ml Cartridges & Penfills & Prefilled syringes
4	Biphasic Isophane Insulin Injection IP (Recombinant DNA origin) Monocomponent Insulin (Human) 100 IU/mL (50/50)	Each mL contains: Human Insulin IP 100 IU (50% Soluble Insulin Injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 1.5 ml & 3 ml Cartridges. & Penfills & Pre filled Syringes
5	Biphasic Isophane Insulin Injection IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 40 IU/mL (30/70)	Each mL contains: Human Insulin IP 40 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 ml vial
6	Biphasic Isophane Insulin Injection IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL (30/70)	Each Dispopen contains one 3 mL cartridge of Biphasic Isophane Insulin Injection IP 100 IU/ml. Each ml contains: Human Insulin (30% Soluble Insulin Injection and 70% Isophane Insulin Injection) IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Dispopen containing 3 ml cartridge.



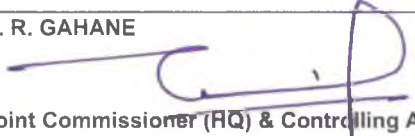

 Joint Commissioner (M.D.A.)
 Food and Drugs Administration,
 Maharashtra State, Mumbai

7	Biphasic Isophane Insulin Injection IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL (30/70)	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 ml, 5 ml & 3 ml Vial
8	Biphasic Isophane Insulin Injection IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL (50/50)	Each Dispopen contains one 3 mL cartridge of Biphasic Isophane Insulin Injection IP 100 IU/ml. Each ml contains: Human Insulin (50% Soluble Insulin Injection and 50% Isophane Insulin Injection) IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Dispopen containing 3 ml cartridge.

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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
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Name of the Authorised person : **D. R. GAHANE**

Signature : 
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025



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No. of certificate : NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427 **VALID UPTO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
9	Biphasic Isophane Insulin Injection IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL (50/50)	Each mL contains: Human Insulin IP 100 IU (50% soluble Insulin injection & 50% Isophane Insulin Injection) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 ml Vial
10	Biphasic Isophane Insulin Injection IP (Recombinant DNA origin) Monocomponent Insulin (Human)40 IU/mL (50/50)	Each mL contains: Human Insulin IP 40 IU (50% soluble Insulin injection & 50% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 10 ml vial.
11	BIPHASIC ISOPHANE INSULIN INJECTION IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL, 30/70	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection and 70% Isophane Insulin Injection) m-Cresol USP 0.16% w/v as Preservatives Phenol IP 0.065% w/v as Preservatives Water for Injections IP QS Pack: 3 ml, 5 ml, 10 ml Vials along with two Syringes
12	BIPHASIC ISOPHANE INSULIN INJECTION IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL, 50/50	Each mL contains: Human Insulin IP 100 IU (50% Soluble Insulin Injection and 50% Isophane Insulin Injection) m-Cresol USP 0.16% w/v as Preservatives Phenol IP 0.065% w/v as Preservatives Water for Injections IP QS Pack: 3 ml, 5 ml, 10 ml Vials along with two Syringes
13	BIPHASIC ISOPHANE INSULIN INJECTION IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 40 IU/mL, 30/70	Each mL Contains: Human Insulin IP 40 IU (30% Soluble insulin Injection and 70% Isophane Insulin Injection) m-Cresol USP 0.16% w/v as Preservatives Phenol IP 0.065% w/v as Preservatives Water for Injections IP QS Pack: 10 mL Vials along with two Syringes
14	BIPHASIC ISOPHANE INSULIN INJECTION IP (Recombinant DNA Origin) Monocomponent Insulin (Human) 40 IU/mL, 50/50	Each mL contains: Human Insulin IP 40 IU (50% Soluble Insulin Injection and 50% Isophane Insulin Injection) m-Cresol USP 0.16% w/v as Preservatives Phenol IP 0.065% w/v as Preservatives Water for Injections IP QS Pack: 10 mL Vials along with two Syringes



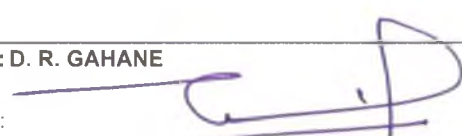
[Signature]
Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

15	Erythropoietin Injection IP 10000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 10000 IU With HSA Stabilizer Aqueous buffer qs Pack: 1 ml Pre-filled Syringe
16	Erythropoietin Injection IP 10000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 10000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe fitted with UltraSafe Passive Needle Guard

1 2 3 4 5 6 7 8 9 10 ...

Address of certifying authority :
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Bandra-kurla Complex,
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Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
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Name of the Authorised person : **D. R. GAHANE**

Signature : 
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025



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No. of certificate : NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427 VALID UPTO :10 Aug 2028

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBAHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
17	Erythropoietin Injection IP 12000 IU (Recombinant DNA Origin)	Each 3 mL Vial contains: Erythropoietin Concentrated Solution IP 12000 IU With HSA Stabilizer Benzyl Alcohol IP (as Preservative) Aqueous Buffer qs Pack: 3 ml Multi-dose Vial
18	Erythropoietin Injection IP 2000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 2000 IU With HSA Stabilizer Aqueous buffer qs Pack: 0.5 ml Pre-filled Syringe
19	Erythropoietin Injection IP 2000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 2000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard
20	Erythropoietin Injection IP 2000 IU (Recombinant DNA Origin)	Each 1 mL Vial contains: Erythropoietin Concentrated Solution IP 2000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Vial
21	Erythropoietin Injection IP 20000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 20000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe
22	Erythropoietin Injection IP 3000 IU (Recombinant DNA Origin)	Each 0.3 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 3000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.3 ml Pre-filled Syringe
23	Erythropoietin Injection IP 3000 IU (Recombinant DNA Origin)	Each 0.3 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 3000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.3 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard
24	Erythropoietin Injection IP 30000 IU (Recombinant DNA Origin)	Each 3 mL Cartridge for Pen contains: Erythropoietin Concentrated Solution IP 30000 IU With HSA Stabilizer Benzyl Alcohol IP (as Preservative) Aqueous Buffer qs Pack: 3 ml Multi-dose Cartridge



1 2 3 4 5 6 7 8 9 10 ...

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Fax: +91-22-26591959
ICOWS1715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature : _____
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- GMP/CERT/AD/150740/2025/11/56427 **VALID UP TO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
25	Erythropoietin Injection IP 4000 IU (Recombinant DNA Origin)	Each 0.4 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.4 ml Pre-filled Syringe
26	Erythropoietin Injection IP 4000 IU (Recombinant DNA Origin)	Each 0.4 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.4 ml Pre-filled Syringe fitted with UltraSafe Passive Needle Guard
27	Erythropoietin Injection IP 4000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe
28	Erythropoietin Injection IP 4000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe fitted with UltraSafe Passive Needle Guard
29	Erythropoietin Injection IP 4000 IU (Recombinant DNA Origin)	Each 1 mL Vial contains: Erythropoietin Concentrated Solution IP 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Vial
30	Erythropoietin Injection IP 40000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 40000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe
31	Erythropoietin Injection IP 5000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution IP 5000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe fitted with UltraSafe Passive Needle Guard
32	Human Insulin Isophane Suspension and Human Insulin Injection USP 100 IU/mL (Recombinant DNA origin) Monocomponent Insulin Human	Each mL contains: Insulin Human USP 100 IU (30% Insulin Human neutral and 70% Isophane Insulin) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml, 5 ml, 3 ml Vial. 1.5 ml & 3 ml Cartridges & Pre filled Syringes



1 2 3 4 5 6 7 8 9 10 ...

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Bandra-kurla Complex,
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Fax: +91-22-26591959
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WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature : 
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority,**
Food & Drug Administration, M.S.
Bandra (E), Mumbai,
Maharashtra State, India
Date:11 Aug 2025

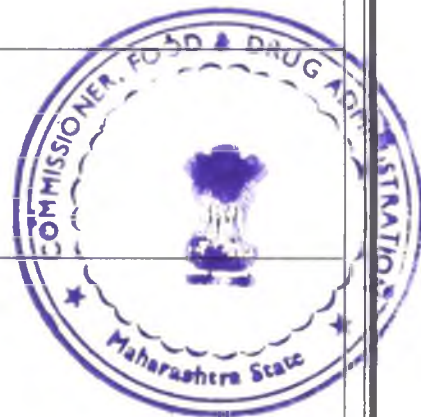
LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- GMP/CERT/AD/150740/2025/11/56427 **VALID UP TO :10 Aug 2028**

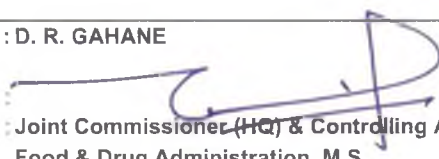
Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
33	Insulin Glargine 100 IU/mL, Solution for Injection (SC), (Recombinant DNA Origin)	Each pen delivery device contains one 3 mL cartridge of Insulin Glargine Each ml of cartridge contains: Insulin Glargine (rDNA) 100 IU m-Cresol USP 0.27% w/v Water for Injection qs Pack : Pen delivery device contains one 3 ml Cartridge One unit of sterile Disposable needle provided to be used with Insulin Glargine pen delivery device
34	Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each Dispopen contains one 3mL Cartridge of Insulin Glargine IP 100 IU/ml Each ml contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: Dispopen containing 3 ml cartridge
35	Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each Dispopen contains one 3mL Cartridge of Insulin Glargine IP 100 IU/ml Each ml contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: Dispopen containing 3 ml cartridge One unit of Disposable Hypodermic Needle provided to be used with this Product
36	Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: 3 ml Cartridge
37	Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: 10 ml Vial
38	Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: 10 ml vial with two hypodermic syringes with needle
39	Insulin Glargine Injection IP 40 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine IP 40 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: 10 ml Vial



(Signature)
Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

40	Insulin Human Injection USP 100 IU/mL, Human Recombinant (r-DNA) Insulin, Regular (Soluble/Neutral)	Each mL contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack: 10 ml, 5 ml, 3 ml Vial. 1.5 ml & 3 ml Cartridges & Pre filled Syringes
<u>1 2 3 4 5 6 7 8 9 10 ...</u>		
Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai – 400 051. Maharashtra, INDIA. Tel: +91-22-26592363/64 Fax: +91-22-26591959 1COWS1715074020250811 WOCKHARDT LIMITED - NEW-WHO- GMP/CERT/AD/150740/2025/11/56427		Name of the Authorised person : D. R. GAHANE Signature :  Stamp and Date : Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S. Bandra (E), Mumbai. Maharashtra State, India Date: 11 Aug 2025



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

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Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
41	Insulin Injection IP (Recombinant DNA Origin) 100 IU/mL (Regular) Monocomponent Insulin (HUMAN)	Each mL contains: Human Insulin IP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injections IP qs Pack: 3 ml Cartridge.
42	Insulin Injection IP (Recombinant DNA Origin) (Regular / Neutral) Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Insulin Injection IP 100 IU/ml. Each ml contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection IP qs Pack: Dispopen containing 3 ml cartridge.
43	INSULIN INJECTION IP (Recombinant DNA Origin) (Regular /Neutral) Monocomponent Insulin (Human) 100 IU/mL	Each mL contains: Human Insulin IP 100 IU m-Cresol (as Preservatives) USP 0.25% w/v (as Preservatives) Water for Injections IP QS Pack: 3 ml, 5 ml, 10 ml Vials along with two Syringes
44	INSULIN INJECTION IP (Recombinant DNA Origin) (Regular /Neutral) Monocomponent Insulin (Human) 40 IU/mL	Each mL contains: Human Insulin IP 40 IU m-Cresol USP 0.25% w/v as Preservatives Water for Injections IP QS Pack: 10 mL Vials along with two Syringes
45	Insulin Injection IP Recombinant DNA Origin Regular / Neutral Monocomponent Insulin (Human) 100 IU/mL	Each mL contains: Human Insulin IP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injections IP qs Pack: 1.5 ml & 3 ml Cartridges & Penfills & Pre filled syringes
46	Insulin Injection IP Recombinant DNA Origin Regular/Neutral Monocomponent Insulin (Human) 40 IU/mL	Each mL contains: Human Insulin IP 40 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection IP qs Pack: 10 ml vial
47	Insulin Injection IP Recombinant DNA Origin Regular/Neutral Monocomponent Insulin (Human) 100 IU/mL	Each mL contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injections IP qs Pack: 10 ml Vial
48	Isophane Insulin Human Suspension USP Recombinant DNA origin, Monocomponent Insulin-NPH	Each mL of isophane suspension contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for injection USP qs Pack: 10 ml, 5 ml, 3 ml Vial. 1.5 ml & 3 ml Cartridges & Pre filled Syringes



1 2 3 4 5 6 7 8 9 10 ...

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WOCKHARDT LIMITED - NEW-WHO-
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Signature : 
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Food & Drug Administration, M.S.
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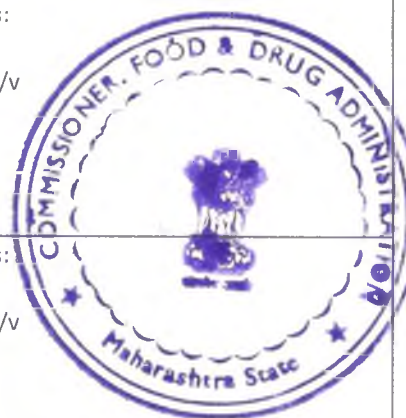
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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
49	Isophane Insulin Injection IP (Recombinant DNA origin) 100 IU/mL, (Isophane) Monocomponent Insulin (HUMAN)	Each mL contains: Human Insulin IP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 3 ml Cartridge.
50	Isophane Insulin Injection IP (Recombinant DNA Origin) NPH - Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Isophane Insulin Human Suspension IP 100 IU/ml. Each ml contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: Dispopen containing 3 ml cartridge.
51	Isophane Insulin Injection IP (Recombinant DNA origin) NPH- Monocomponent Insulin (Human) 100 IU/mL	Each mL of Isophane suspension contains: Human Insulin IP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 1.5 ml & 3 ml Cartridges & Penfills & Pre filled syringes
52	Isophane Insulin Injection IP (Recombinant DNA Origin) NPH- Monocomponent Insulin (Human) 100 IU/mL	Each mL of Isophane suspension contains: Human Insulin IP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 ml, 5 ml Vial
53	Isophane Insulin Injection IP (Recombinant DNA Origin) NPH- Monocomponent Insulin (Human) 40 IU/mL	Each mL of Isophane suspension contains: Human Insulin IP 40 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) IP 0.065 % w/v Water for Injections IP qs Pack: 10 ml vial
54	ISOPHANE INSULIN INJECTION IP (Recombinant DNA Origin) NPH- Monocomponent Insulin (Human) 100 IU/mL	Each mL of Isophane Suspension Contains: Human Insulin IP 100 IU m-Cresol USP 0.16% w/v as Preservatives Phenol IP 0.065% w/v as Preservatives Water for Injections IP QS Pack: 3 ml, 5 ml, 10 ml Vials along with two Syringes



(Signature)
Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

55	ISOPHANE INSULIN INJECTION IP (Recombinant DNA Origin) NPH- Monocomponent Insulin (Human) 40 IU/mL	Each mL of Isophane Suspension Contains: Human Insulin IP 40 IU m-cresol USP 0.16% w/v as Preservatives Phenol IP 0.065% w/v as Preservatives Water for Injections IP QS Pack: 10 ml Vials along with two Syringes
56	Recombinant Human Erythropoietin Injection 10000 IU	Each 1 mL pre filled syringe contains: Recombinant Human Erythropoietin IP 10000 IU With HSA Stabilizer Pack: 1 ml pre filled syringe

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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025



LIST OF PRODUCT APPROVED UNDER WHO GMP

No. of certificate : NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427
VALID UP TO :10 Aug 2028

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

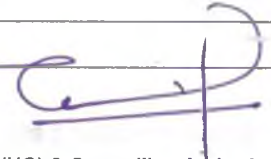
Sr.No.	Name of the Product	Composition
57	Recombinant Human Erythropoietin Injection 12000 IU	Each Cartridge (1.2 mL) for pen contains: Recombinant Human Erythropoietin Ph.Eur 12000 IU With HSA as Stabilizer Aqueous Buffer qs Pack: Cartridge multidose container
58	Recombinant Human Erythropoietin Injection 12000 IU	Each Vial (3 mL) contains: Recombinant Human Erythropoietin Ph.Eur 12000 IU With HSA as Stabilizer Aqueous Buffer qs Pack: Vial multidose container
59	Recombinant Human Erythropoietin Injection 2000 IU	Each 0.5 mL pre-filled syringe contains: Recombinant Human Erythropoietin IP 2000 IU With HSA Stabilizer Pack: 0.5 ml Pre-filled Syringe
60	Recombinant Human Erythropoietin Injection 2000 IU	Each vial (0.5 mL) contains: Recombinant Human Erythropoietin Ph.Eur 2000 IU With HSA Stabiliser Aqueous buffer qs Pack: vial single dose container
61	Recombinant Human Erythropoietin Injection 2000 IU	Each vial (1 mL) contains: Recombinant Human Erythropoietin IP 2000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml vial
62	Recombinant Human Erythropoietin Injection 30,000 IU	Each Cartridge (3 mL) for pen contains: Recombinant Human Erythropoietin Ph.Eur 30000 IU With HSA Stabilizer Aqueous buffer qs Pack: Cartridge Multi dose container.
63	Recombinant Human Erythropoietin Injection 3000 IU	Each 0.3 mL pre filled Syringe contains: Recombinant Human Erythropoietin IP 3000 IU With HSA Stabilizer Pack: 0.3 ml Pre-filled Syringe
64	Recombinant Human Erythropoietin Injection 4000 IU	Each 0.4 mL and 1 mL pre-filled syringe contains: Recombinant Human Erythropoietin IP 4000 IU With HSA Stabilizer Pack: Pre-filled Syringe



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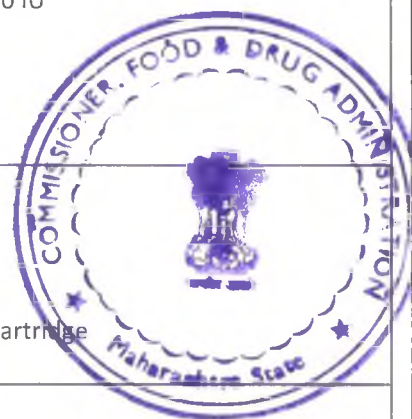
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CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
65	Recombinant Human Erythropoietin Injection 4000 IU	Each vial (1 mL) contains: Recombinant Human Erythropoietin Ph.Eur 4000 IU With HSA Stabilizer Aqueous buffer qs Pack: 1 ml vial
66	Recombinant Human Erythropoietin Injection 4000 IU	Each vial (1 mL) contains: Recombinant Human Erythropoietin IP 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml vial
67	RECOMBINANT INSULIN GLARGINE INJECTION 100 IU/mL	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection USP qs Pack: 10 ml, 5 ml, 3 ml vial. 1.5 ml & 3 ml Cartridge
68	Recombinant Insulin Glargine Injection 100 IU/mL	Each mL contains: Insulin Glargine 100 IU (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Excipients: Glycerol (85%), Zinc Chloride, m-Cresol, Sodium Hydroxide, Hydrochloric Acid, Water for Injection q.s. to 1 ml Pack: 10 ml vial, 3 ml cartridge
69	Recombinant Insulin Glargine Injection 100 IU/mL	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection IP qs Pack: One 3 ml cartridge, one Pen device & one 5 mm pentip.
70	Recombinant Insulin Glargine Injection 100 IU/mL	Each mL contains; Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection IP qs Pack: 10 ml vial along with 2 disposable syringes.
71	WOZULIM - 30/70 100 IU/mL Biphasic Isophane Insulin Injection BP Recombinant DNA origin. Monocomponent Insulin.	Each mL contains: Insulin Human USP 100 IU (30% Insulin Human neutral & 70% Isophane Insulin) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial, 5 ml vial and 3 ml vial.1.5 ml & 3 ml Cartridge, & Penfills & Pre filled syringes.



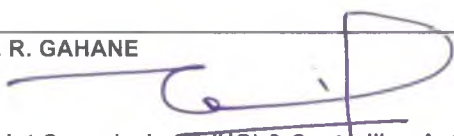
Joint Commissioner (H.O.)
Food and Drugs Administration,
Maharashtra State, Mumbai

72	Recombinant Insulin Glargine Injection 100 IU/mL	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injections IP qs Pack: 3 ml cartridge.
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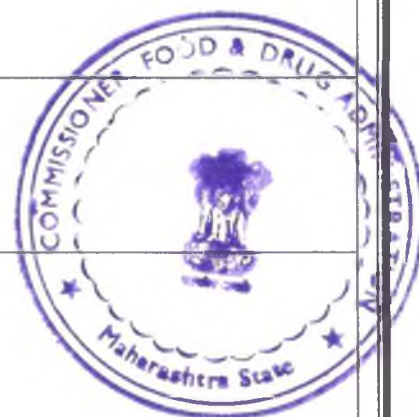
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MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
73	ERYTHINE 4000 Recombinant Human Erythropoietin 4000 IU/0.4mL Solution for Injection	Each 0.4 mL Pre-filled Syringe contains: Recombinant Human Erythropoietin 4000 IU With HSA as stabiliser Pack : Pre-filled Syringe
74	ETHROTIN 4000 Recombinant Human Erythropoietin 4000 IU/0.4mL Solution for Injection	Each 0.4 mL Pre-filled Syringe contains: Recombinant Human Erythropoietin 4000 IU With HSA as stabiliser Pack: Pre filled Syringe
75	GLAINE 100 IU/mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injection USP qs Pack: 3 ml Cartridge
76	GLAINE DISPOPEN RECOMBINANT INSULIN GLARGINE INJECTION 100 IU/mL	Each GLAINE Dispopen contains one 3 mL cartridge of Recombinant Insulin Glargine Injection 100 IU/mL Each ml contains: Insulin Glargine 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injection USP qs 1 unit of sterile disposable needle provided with GLAINE Dispopen Pack: Pen device containing 3 ml cartridge
77	GLARITUS Insulin Glargine 100IU/mL Solution for Injection	Each mL contains: Insulin Glargine (rDNA) 100 IU m-cresol USP 0.27 % w/v Water for Injection QS Pack: 10 ml Vial
78	GLARITUS Insulin Glargine 100IU/mL Solution for Injection	Each Pen Delivery Device Contains one 3 mL Cartridge of Insulin Glargine Each mL of Cartridge Contains Insulin Glargine (rDNA) 100 IU m-cresol USP 0.27 % w/v Water for Injection QS 1 unit of Sterile Disposable Needle Provided to be used with Glaritus Pen Delivery Device. Pack: 3 ml Cartridge With Pen Delivery Device
79	GLARITUS Insulina Glargina(recombinant DNA origin)Recombinant Insulin Glargine Injection 100 U/mL Solution for injection	Each cartridge of 3 mL contains : Insulin Glargine 300 IU (equivalent to 10.92 mg) corresponding to 300 IU of Human Insulin Excipients : Glycerol 85%,Zinc Chloride ,m-Cresol, Sodium Hydroxide ,Hydrochloric Acid,Water for Injection q.s.to 3 mL Each mL contains 100 U of Insulin Glargine (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Pack: 3 mL cartridge



(Signature)
Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

80	GLARITUS 100 IU / mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection USP qs Pack: 10 ml Vial
1 2 3 4 5 6 7 8 9 10 ...		

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Food & Drug Administration, M.S.
Bandra (E), Mumbai.
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CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

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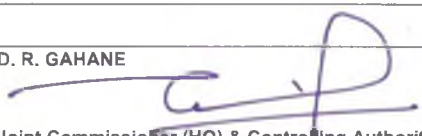
Sr.No.	Name of the Product	Composition
81	GLARITUS 100 IU / mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection USP qs Pack: 10 ml Vial along with 2 disposable syringes.
82	GLARITUS 100 IU/mL Insulin Glargine Injection BP 100 IU/mL (Recombinant DNA origin)	Each mL contains : Insulin Glargine Ph.Eur 100 IU m-Cresol Ph.Eur 0.27 % w/v (as preservative) Water for Injection Ph.Eur qs Pack : 3 mL Cartridge
83	Glaritus 100 IU/mL Insulin Glargine Injection BP 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine Ph.Eur 100 IU m-Cresol Ph.Eur 0.27 % w/v (as preservative) Water for Injection Ph.Eur qs Pack : 10 mL Vial
84	GLARITUS 100 IU/mL Insulin Glargine Injection BP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine Ph.Eur 100 IU m-Cresol Ph.Eur. 0.27 % w/v (as preservative) Water for Injections Ph.Eur qs Pack: 10 ml vial with two hypodermic syringes with needle
85	GLARITUS 100 IU/mL Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each Dispopen contains one 3 mL cartridge of Insulin Glargine Injection IP 100 IU/mL: Each ml contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: Dispopen containing 3 ml cartridge
86	GLARITUS 100 IU/mL Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: 10 ml Vial
87	GLARITUS 100 IU/mL Insulin Glargine Injection IP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine IP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injections IP qs Pack: 3 ml Cartridge
88	Glaritus 100 IU/mL Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine USP 100 IU m-Cresol USP 0.27% w/v (as preservative) Water for Injections USP qs Pack: 10 mL vial



... 11 12 13 14 15 16 17 18 19 20 ...

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1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
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Name of the Authorised person : D. R. GAHANE

Signature : 
Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025

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GMP/CERT/AD/150740/2025/11/56427 **VALID UPTO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
89	Glartus 100 IU/mL Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine USP 100 IU m-Cresol USP 0.27% w/v (as preservative) Water for Injection USP QS Pack: 3 mL Cartridge
90	GLARITUS 100 IU/mL Insulin Glargine Injection USP 100 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine USP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injection USP qs 10 ml vial with two hypodermic syringes with needle
91	GLARITUS 100 IU/mL Insulin Glargine Injection USP 40 IU/mL, (Recombinant DNA Origin)	Each mL contains: Insulin Glargine USP 40 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injection USP qs Pack: 10 ml Vial
92	GLARITUS 100 IU/mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Excipients: Glycerol (85%), Zinc Chloride, m-Cresol, Sodium Hydroxide, Hydrochloric Acid, Water for Injection q.s. to 3 ml Pack: 10 ml vial, 3 mL Cartridge
93	GLARITUS CARTRIDGE 100 IU / mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection USP qs Pack: 3mL Cartridge.
94	GLARITUS CARTRIDGE 100 IU/mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Excipients: Glycerol (85%), Zinc Chloride, m-Cresol, Sodium Hydroxide, Hydrochloric Acid, Water for Injection q.s. to 1 ml Pack: 3 ml Cartridge
95	GLARITUS DISOPEN Insulin Glargine Injection BP 100 IU/mL, (Recombinant DNA Origin)	Each Dispopen contains one 3mL Cartridge of Insulin Glargine BP 100 IU/mL Each ml contains: Insulin Glargine Ph.Eur 100 IU m-Cresol Ph.Eur. 0.27 % w/v (as preservative) Water for Injections Ph.Eur qs Pack: Dispopen containing 3 ml cartridge One unit of Disposable Hypodermic Needle provided to be used with this Product



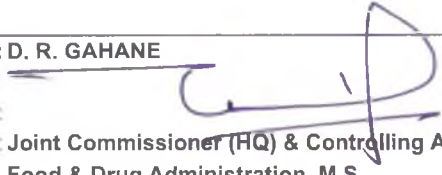
[Signature]
Joint Commissioner (B.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

96	Glaritus Dispopen Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA origin)	Each Dispopen contains: one 3 mL cartridge of Insulin Glargine Injection USP 100 IU/mL Each mL contains: Insulin Glargine USP 100 IU m-Cresol USP 0.27% w/v (as preservative) Water for Injection USP qs Pack: Dispopen containing 3 mL Cartridge
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MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
97	GLARITUS DISPOPEN Insulin Glargine Injection USP 100 IU/mL, (Recombinant DNA Origin)	Each Dispopen contains one 3mL Cartridge of Insulin Glargine USP 100 IU/mL Each ml contains: Insulin Glargine USP 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge One unit of Disposable Hypodermic Needle provided to be used with this Product
98	Glaritus Dispopen Insulina Glargina (Recombinant DNA origin)Recombinant Insulin Glargine Injection 100 U/mL Solution for Injection	Each Glaritus Dispopen with cartridge of 3 mL contains : Insulin Glargine 300 U (equivalent to 10.92 mg) corresponding to 300 IU of Human Insulin Excipients : Glycerol 85%,Zinc Chloride ,m-Cresol,Sodium Hydroxide ,Hydrochloric Acid,Water for Injection q.s.to 3 mL Each ml contains 100 IU of Insulin Glargine(equivalent to 3.64 mg) corresponding to 100 IU of Human insulin Pack :Dispopen containing 3 mL Cartridge
99	GLARITUS DISPOPEN Recombinant Insulin Glargine Injection 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Recombinant Insulin Glargine Injection Each ml contains: Insulin Glargine 100 IU m-Cresol (as preservative) USP 0.27 % w/v Water for Injection USP qs Pack : Dispopen containing 3 mL Cartridge One unit of sterile disposable needle provided to be used with Glaritus Dispopen
100	GLARITUS DISPOPEN Recombinant Insulin Glargine Injection	Each Glaritus Dispopen with cartridge of 3 mL contains: Insulin Glargine 300 IU (equivalent to 10.92 mg) corresponding to 300 IU of Human Insulin Excipients: Glycerol (85%), Zinc Chloride, m-Cresol, Sodium Hydroxide, Hydrochloric Acid, Water for Injection q.s. to 1 ml Pack: Dispopen containing 3 ml cartridge.
101	GLARITUS DISPOPEN 100 IU / mL Recombinant Insulin Glargine Injection	Each mL contains: Insulin Glargine 100 IU m-Cresol USP (as preservative) 0.27 % w/v Water for Injection USP qs Pack: One 3 ml cartridge, one Pen device & one 5 mm pentip
102	Glaritus Dispopen. Insulin Glargine Injection BP 100 IU/mL(Recombinant DNA origin)	Each Dispopen contains : one 3 mL cartridge of Insulin Glargine Injection BP 100 IU/ml Each mL contains : Insulin Glargine Ph.Eur 100 IU m-Cresol Ph.Eur 0.27 % w/v (as preservative) Water for Injection Ph.Eur qs Pack : Dispopen containing 3 mL cartridge



[Signature]
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Food and Drugs Administration
Maharashtra State, Mumbai

103	Glaritus. Insulin Glargine Injection USP 100 IU/mL (r-DNA Origin)	Each mL contains : Insulin Glargine Ph.Eur 100 IU m-Cresol USP 0.27 % w/v (as preservative) Water for Injection USP qs For Subcutaneous use only Pack : 10 mL Vial, 3 mL Cartridge, Dispopen - 2 containing 3 mL Cartridge)
104	GLARSULIN Insulin Glargine 100 IU/mL, Solution for Injection (SC), (Recombinant DNA Origin)	Each pen delivery device contains one 3 mL cartridge of Insulin Glargine Each ml of cartridge contains: Insulin Glargine (rDNA) 100 IU m-Cresol USP 0.27 % w/v Water for Injection qs Pack : Pen delivery device contains one 3 ml Cartridge One unit of sterile Disposable needle provided to be used with Glarsulin pen delivery device

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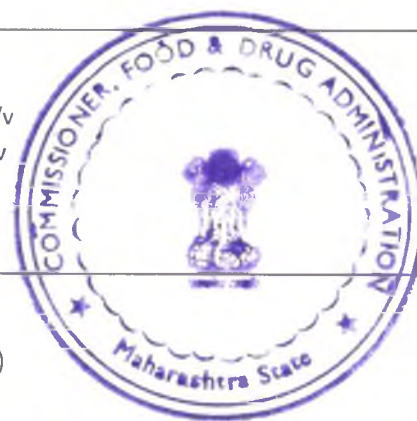
LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- GMP/CERT/AD/150740/2025/11/56427 **VALID UPTO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
105	Glinux-N Isophane Insulin Human Suspension USP 100 IU/mL (Recombinant DNA Origin)	Each mL of Isophane Suspension contains: Insulin Human Ph.Eur 100 IU m-Cresol USP 0.16 % w/v (as preservative) Phenol USP 0.065% w/v (as preservative) Water for Injection USP qs Pack : 10 mL Vial For Subcutaneous use only Monocomponent Insulin NPH
106	GLYSOLIN 30/70 Biphasic Isophane Insulin (Recombinant DNA Origin) 100 IU/mL	Each mL contains: Human Insulin USP 100 IU (30% Human Insulin Neutral and 70% Isophane Insulin) m-Cresol (as Preservatives) 0.16 % w/v Phenol (as Preservatives) 0.065 % w/v Water for Injection QS Pack: 10 ml Vial
107	GLYSOLIN G Insulin Glargine 100 IU/mL, Solution for Injection (SC), (Recombinant DNA Origin)	Each pen delivery device contains one 3 mL cartridge of Insulin Glargine Each ml of cartridge contains: Insulin Glargine (rdNA) 100 IU m-Cresol USP 0.27% w/v Water for Injection qs Pack : Pen delivery device contains one 3 ml Cartridge One unit of sterile Disposable needle provided to be used with GLYSOLIN G pen delivery device
108	GLYSOLIN N Isophane Insulin Human (Recombinant DNA Origin) 100 IU/mL	Each mL contains: Human Insulin USP 100 IU m-Cresol (as Preservatives) 0.16 % w/v Phenol (as Preservatives) 0.065 % w/v Water for Injection QS Pack: 10 ml Vial
109	GLYSOLIN R Regular Insulin Human (Recombinant DNA Origin) 100 IU/mL	Each mL Contains: Human Insulin USP 100 IU m-cresol 0.25% w/v (as Preservatives) Water for Injection QS Pack: 10 ml Vial
110	INSULINA 30/70 Insulina Iofena Bifesica (Recombinant DNA origin.) Suspension Injectable 100 IU/mL. Wozulim 30/70	Each mL contains: Insulin Human 100 IU (30% Insulin Human regular neutral & 70% Isophane Insulin) Vehicle qs to 1 ml Pack: 3 ml Cartridges.
111	INSULINA N Insulina Humana (Recombinant DNA) Suspension 100 IU/mL Injectable Wozulim N	Each mL contains: Insulin Human 100 IU Vehicle qs to 1 ml Pack: 3 ml Cartridges




 Joint Commissioner (H.Q.)
 Food and Drugs Administration
 Maharashtra State, Mumbai

112	INSULINA R Insulina Humana (Recombinant DNA origin) Solution Injectable 100 IU/mL Wozulim R	Each mL contains: Insulin Human recombinant DNA 100 IU Vehicle qs to 1 ml Pack: 3 ml Cartridges.
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Address of certifying authority :
Food & Drug Administration, M.S.

Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.

Tel: +91-22-26592363/64

Fax: +91-22-26591959

1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

Date: 11 Aug 2025



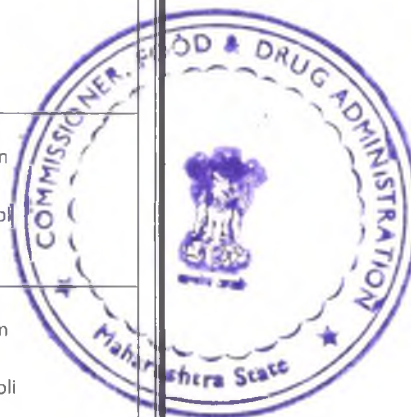
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Sr.No.	Name of the Product	Composition
113	INSULINA Humana Injection USP (Recombinant DNA) R Solution 100 IU/mL Injectable Wozulim R	Each mL contains: Insulin Human (recombinant DNA USP) 100 IU Vehicle qs to 1 ml Pack: 10 ml vial.
114	INSULINA Humana isophane Insuline Human Suspension USP (Recombinant DNA) 100 IU/mL Injectable Wozulim N	Each mL contains: Insulin Human USP 100 IU Vehicle qs to 1 ml Pack: 10 ml vial.
115	INSULINA Isofana Bifasica 30/70 (Recombinant DNA origin). Suspension Injectable 100 IU/mL. Wozulim 30/70	Each mL contains: Insulin Human USP 100 IU(30% insulin Human regular neutral & 70% Isophane Insulin) Vehicle qs to 1 ml Pack 10 ml vial.
116	Recombinant Insulin Glargine Injection 100 IU/mL Insulina Glargina(recombinant DNA origin) Solution for injection	Each cartridge of 3 mL contains: Insulin Glargine 300 IU (equivalent to 10.92 mg) corresponding to 300 IU of Human Insulin Excipients: Glycerol (85%), Zinc Chloride, m-Cresol, Sodium Hydroxide, Hydrochloric Acid, Water for Injection q.s. to 3 ml Each ml contains 100 IU of Insulin Glargine (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Pack: 3 ml cartridge
117	VALVEY Insulin Glargine, Solution 100 IU/mL, Injectable	Each mL contains: Insulin Glargine 3.64 mg. Equivalent to 100 IU of Insulin Human Vehicle qs to 1 ml Insulin of recombinant DNA origin, expression in Escherichia coli Pack: 10 mL vial
118	VALVEY Insulin Glargine, Solution 100 IU/mL, Injectable	Each mL contains: Insulin Glargine 3.64 mg. Equivalent to 100 IU of Insulin Human Vehicle qs to 1 ml Insulin of recombinant DNA origin, expression in Escherichia coli Pack: One 3mL Cartridge
119	VALVEY DISPOPEN Insulin Glargine, Solution 100 IU/mL, Injectable	Each mL contains: Insulin Glargine 3.64 mg. Equivalent to 100 IU of Insulin Human Vehicle qs to 1 ml Insulin of recombinant DNA origin, expression in Escherichia coli Pack: One Dispopen containing 3mL Cartridge
120	VIMINOVA Insulin Glargine Injection USP 100 IU / mL (Recombinant DNA Origin)	Each mL contains : Insulin Glargine USP 100 IU m-Cresol USP 0.27% w/v(as preservative) Water for injection USP QS Pack : 10 mL Vial



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WOCKHARDT LIMITED - NEW-WHO-
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Name of the Authorised person : **D. R. GAHANE**

Signature : 
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
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Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
121	VIMINOVA Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA Origin)	Each mL contains : Insulin Glargine USP 100 IU m-Cresol USP 0.27% w/v(as preservative) Water for injection USP QS Pack : 3 mL Cartridge
122	VIMINOVA DISPOPEN Insulin Glargine Injection USP 100 IU/mL (Recombinant DNA Origin)	Each Dispopen contains: One 3 mL cartridge of Insulin Glargine Injection USP 100 IU/mL Each ml contains : Insulin Glargine USP 100 IU m-Cresol USP 0.27% w/v(as preservative) Water for injection USP QS Pack : Dispopen containing 3 ml cartridge
123	VITASULIN - 30/70 100 IU/mL Biphasic Isophane Insulin Injection BP Recombinant DNA origin	Each mL contains: Insulin Human USP 100 IU (30% Regular Insulin Human neutral & 70% Isophane Insulin) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial, 3 ml cartridge
124	VITASULIN - N 100 IU/mL Isophane Insulin Human Suspension USP Recombinant DNA origin	Each mL of Isophane suspension contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial, 3 ml cartridge.
125	VITASULIN - R 100 IU/mL Insulin Human Injection USP Recombinant DNA origin	Each mL contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack: 10 ml vial, 3 ml cartridge.
126	WEPOX - 5000 Recombinant Human Erythropoietin Injection 5000 IU	Each 0.5 mL pre filled syringe contains: Recombinant Human Erythropoietin 5000 IU with HSA as Stabilizer Pack: Pre filled syringe
127	Wepox 10000 IU Erythropoietin Injection BP 10000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 10000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe
128	Wepox 12000 IU Erythropoietin Injection BP 12000 IU (Recombinant DNA Origin)	Each 3 mL Vial contains: Erythropoietin Concentrated Solution Ph.Eur 12000 IU With HSA Stabilizer Benzyl Alcohol Ph.Eur. (as Preservative) Aqueous Buffer qs Pack: 3 ml Multi-dose Vial



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Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025

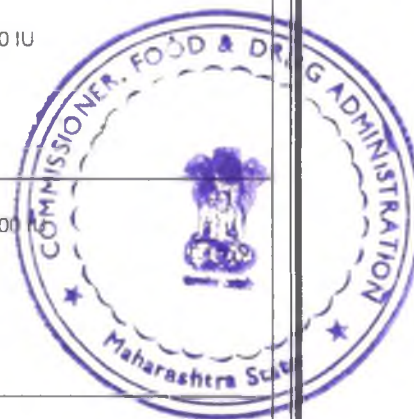
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CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
129	WEPOX 2000 Recombinant Human Erythropoietin Injectable Solution 0.5 mL	Each prefilled syringe with 0.5 mL contains: Erythropoietin Concentrated Solution (rdNA) 2000 IU Excipients q.s.
130	Wepox 2000 IU Erythropoietin Injection BP 2000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 2000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 mL Pre-filled Syringe
131	Wepox 2000 IU Erythropoietin Injection BP 2000 IU (Recombinant DNA Origin)	Each 1 mL Vial contains: Erythropoietin Concentrated Solution Ph.Eur 2000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Vial
132	Wepox 20000 IU Erythropoietin Injection BP 20000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 20000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe
133	Wepox 3000 IU Erythropoietin Injection BP 3000 IU (Recombinant DNA Origin)	Each 0.3 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 3000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.3 ml Pre-filled Syringe
134	Wepox 30000 Recombinant Human Erythropoietin Injection 30000 IU (Recombinant DNA origin)	Each 3mL Cartridge for pen contains Erythropoietin Concentrated Solution Ph.Eur 30000 Benzyl Alcohol Ph.Eur. (As preservative) With HSA Stabilizer Aqueous Buffer Q.S. Pack: 3mL Multi-dose Cartridge
135	Wepox 30000 IU Erythropoietin Injection BP 30000 IU (Recombinant DNA Origin)	Each 3 mL Cartridge for Pen contains: Erythropoietin Concentrated Solution Ph.Eur 30000 IU With HSA Stabilizer Benzyl Alcohol Ph.Eur. (As preservative) Aqueous Buffer qs Pack: 3 ml Multi-dose Cartridge
136	WEPOX 4000 Recombinant Human Erythropoietin Injectable Solution 0.4 mL	Each Prefilled Syringe with 0.4 mL Contains Erythropoietin Concentrated Solution (rdNA) 4000 IU Excipients QS Pack: 0.4 mL Prefilled Syringe



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Name of the Authorised person : **D. R. GAHANE**

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Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:11 Aug 2025

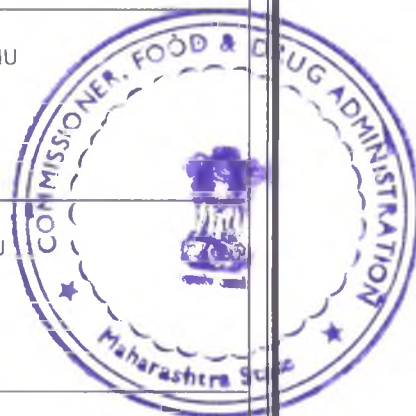
LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-
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VALID UP TO : 10 Aug 2028

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
137	Wepox 4000 IU Erythropoietin Injection BP 4000 IU (Recombinant DNA Origin)	Each 0.4 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.4 ml Pre-filled Syringe
138	Wepox 4000 IU Erythropoietin Injection BP 4000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe
139	Wepox 4000 IU Erythropoietin Injection BP 4000 IU (Recombinant DNA Origin)	Each 1 mL Vial contains: Erythropoietin Concentrated Solution Ph.Eur 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Vial
140	Wepox 40000 IU Erythropoietin Injection BP 40000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 40000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe
141	WEPOX 5000 IU Erythropoietin Injection BP 5000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 5000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe
142	WEPOX SAFE - 10000 Recombinant Human Erythropoietin Injection	Each 1 mL pre-filled syringe contains: Recombinant Human Erythropoietin 10000 IU with HSA as Stabilizer Pack: 1 ml pre-filled syringe fitted with UltraSafe Passive Needle Guard
143	WEPOX SAFE - 2000 Recombinant Human Erythropoietin Injection	Each 0.5 mL pre-filled syringe contains: Recombinant Human Erythropoietin 2000 IU with HSA as stabilizer Pack: 0.5 ml pre-filled syringe fitted with UltraSafe Passive Needle Guard.
144	WEPOX SAFE - 3000 Recombinant Human Erythropoietin Injection	Each 0.3 mL pre-filled syringe contains: Recombinant Human Erythropoietin 3000 IU with HSA as stabilizer Pack: 0.3 ml pre-filled syringe fitted with UltraSafe Passive Needle Guard.



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Address of certifying authority :
Food & Drug Administration, M.S.
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Bandra (E), Mumbai – 400 051.
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Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

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GMP/CERT/AD/150740/2025/11/56427 **VALID UPTO : 10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
145	WEPOX SAFE - 4000 Recombinant Human Erythropoietin Injection	Each 0.4 mL pre-filled syringe contains: Recombinant Human Erythropoietin 4000 IU with HSA as stabilizer Pack: 0.4 ml pre-filled syringe fitted with UltraSafe Passive Needle Guard.
146	WEPOX SAFE - 5000 Recombinant Human Erythropoietin Injection	Each 0.5 mL pre-filled syringe contains; Recombinant Human Erythropoietin 5000 IU with HSA as stabilizer Pack: 0.5 ml pre-filled syringe fitted with UltraSafe Passive Needle Guard.
147	WEPOX SAFE 10000 IU Erythropoietin Injection BP 10000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 10000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe fitted with UltraSafe Passive Needle Guard
148	WEPOX SAFE 2000 IU Erythropoietin Injection BP 2000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 2000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard
149	WEPOX SAFE 3000 IU Erythropoietin Injection BP 3000 IU (Recombinant DNA Origin)	Each 0.3 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 3000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.3 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard
150	WEPOX SAFE 4000 IU Erythropoietin Injection BP 4000 IU (Recombinant DNA Origin)	Each 0.4 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.4 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard
151	WEPOX SAFE 4000 IU Erythropoietin Injection BP 4000 IU (Recombinant DNA Origin)	Each 1 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 1 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard
152	WEPOX SAFE 5000 IU Erythropoietin Injection BP 5000 IU (Recombinant DNA Origin)	Each 0.5 mL Pre-filled Syringe contains: Erythropoietin Concentrated Solution Ph.Eur 5000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard



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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
153	WEPOX-10000 Recombinant Human Erythropoietin Injection 10000 IU	Each 1 mL pre filled syringe contains: Recombinant Human Erythropoietin 10000 IU With HSA as Stabilizer Pack: pre filled syringe
154	WEPOX-2000 Recombinant Human Erythropoietin Injection 2000 IU Solution for Injection	Each 0.5 mL prefilled syringe contains : Recombinant Human Erythropoietin 2000 IU With HSA As Stabilizer Pack : Pre filled syringe
155	WEPOX-20000 Recombinant Human Erythropoietin Injection 20000 IU	Each 0.5 mL pre filled syringe contains: Recombinant Human Erythropoietin 20000 IU With HSA As Stabilizer. Pack: pre filled syringe
156	WEPOX-3000 Recombinant Human Erythropoietin Injection 3000 IU	Each 0.3 mL pre filled Syringe contains: Recombinant Human Erythropoietin 3000 IU With HSA As Stabilizer. Pack: pre filled syringe
157	WEPOX-4000 Recombinant Human Erythropoietin Injection 4000 IU Solution for Injection	Each 0.4 mL pre filled syringe contains : Recombinant Human Erythropoietin 4000 IU With HSA As Stabilizer Pack : Pre filled Syringe
158	WEPOX-40000 Recombinant Human Erythropoietin Injection 40000 IU	Each 1 mL pre filled syringe contains: Recombinant Human Erythropoietin 40000 IU With HSA As Stabilizer. Pack: 1 ml Pre-filled syringe
159	WEPOX-5000 Recombinant Human Erythropoietin Injection 5000 IU	Each 0.5 mL pre filled syringe contains: Recombinant Human Erythropoietin 5000 IU With HSA As Stabilizer. Pack: 0.5 mL pre filled syringe
160	WINSULIN - 30/70 Human Insulin Isophane suspension and Human Insulin Injection USP (Recombinant DNA Origin) 100IU/mL	Each mL contains: Insulin Human USP 100 IU (30% Human Insulin Injection & 70% Human Insulin Isophane Suspension) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial, 3 ml cartridge



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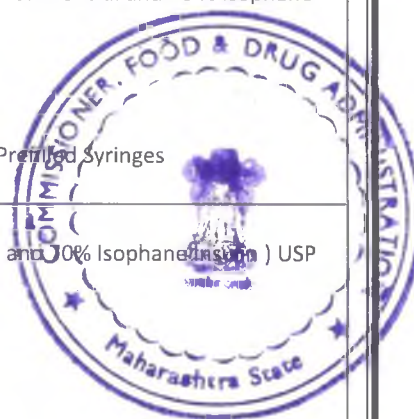
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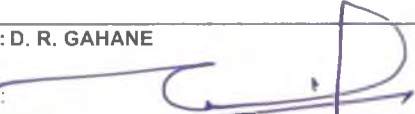
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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
161	WINSULIN - N Isophane Insulin Human Suspension USP (Recombinant DNA Origin) 100 IU/mL	Each mL of contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial, 3 ml cartridge
162	WINSULIN - R Insulin Human Injection USP (Recombinant DNA origin) 100 IU/mL	Each mL contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack: 10 ml vial, 3 ml cartridge
163	WOSULIN – 30/70 100 IU / mL Biphasic Isophane Insulin Injection BP Recombinant DNA origin, Monocomponent Insulin, Suspension for Injection	Each ml contains: Insulin Human USP 100 IU (30% Insulin Human neutral and 70% Isophane Insulin) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 1.5 ml & 3 ml Cartridges. & Penfills & Pre filled Syringes
164	WOSULIN – 30/70 100 IU / mL Biphasic Isophane Insulin Injection BP, Recombinant DNA origin, Monocomponent Insulin, Suspension for Injection	Each mL contains: Insulin Human USP 100 IU (30 % Insulin Human Neutral and 70 % Isophane Insulin) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack : 1.5 ml & 3ml Cartridges & Penfills & Pre filled Syringes
165	WOSULIN – 30/70 100 IU / mL Biphasic Isophane Insulin Injection BP, Recombinant DNA origin, Monocomponent Insulin, Suspension for Injection	Each mL contains: Insulin Human (30% Soluble Insulin Neutral and 70% Isophane Insulin) USP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack : 10 mL Vial, 5ml Vial & 3ml Vial
166	Wosulin – 30/70 100 IU/mL Biphasic Isophane Insulin Injection IP (Recombinant DNA origin), Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection and 70% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 10 ml vial
167	Wosulin – 30/70 100 IU/mL Biphasic Isophane Insulin Injection IP (Recombinant DNA origin), Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU (30% Soluble Insulin Injection and 70% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 3 ml Cartridge



(Signature)
Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

168	WOSULIN – 30/70 40 IU / mL Human Insulin Isophane Suspension and Human Insulin injection USP (Recombinant DNA origin), Monocomponent Insulin, Suspension for Injection	Each mL contains: Insulin Human (30% Soluble Insulin Neutral and 70% Isophane Insulin) USP 40 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack : 10 mL Vial
... 17 18 19 20 21 22 23 24 25 26		
Address of certifying authority : Food & Drug Administration, M.S. Bandra-kurla Complex, Bandra (E), Mumbai – 400 051. Maharashtra,INDIA. Tel: +91-22-26592363/64 Fax: +91-22-26591959 1COW51715074020250811 WOCKHARDT LIMITED - NEW-WHO- GMP/CERT/AD/150740/2025/11/56427		Name of the Authorised person : D. R. GAHANE Signature :  Stamp and Date : Joint Commissioner (HQ) & Controlling Authority Food & Drug Administration, M.S. Bandra (E), Mumbai. Maharashtra State, India Date:11 Aug 2025



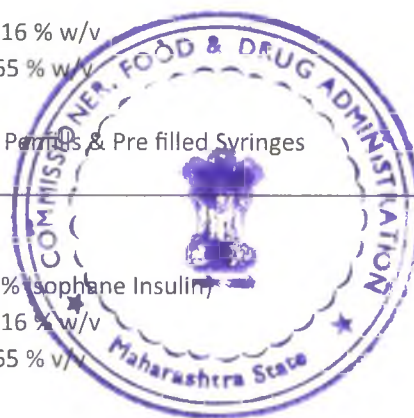
LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427 **VALID UP TO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
169	Wosulin – 30/70 40 IU/mL Biphasic Isophane Insulin Injection IP 40IU/mL (Recombinant DNA origin), Monocomponent Insulin Human	Each mL contains: Human Insulin IP 40 IU (30% Soluble Insulin Injection and 70% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol IP (as preservative) 0.065 % w/v Water for Injections IP qs Pack: 10 ml vial
170	WOSULIN - 50/50 100 IU/mL Biphasic Isophane Insulin Injection BP Recombinant DNA Origin Monocomponent Insulin	Each mL contains: Insulin Human USP 100 IU (50% Insulin Human neutral & 50% Isophane Insulin) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial, 5 ml vial, 3 ml vial
171	WOSULIN - 50/50 100 IU/mL Biphasic Isophane Insulin Injection BP Recombinant DNA origin. Monocomponent Insulin.	Each mL contains: Insulin Human USP 100 IU (50% Insulin Human neutral & 50% Isophane Insulin) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 1.5 ml & 3 ml Cartridges. & Penfills & Pre filled Syringes
172	WOSULIN - 50/50 40 IU/mL Biphasic Isophane Insulin Injection BP Recombinant DNA origin. Monocomponent Insulin	Each mL contains: Insulin Human USP 40 IU (50% Insulin Human neutral & 50% Isophane Insulin) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: 10 ml vial
173	WOSULIN - N 100 IU / mL Isophane Insulin Human Suspension USP Recombinant DNA origin, Monocomponent Insulin- NPH, Suspension for Injection	Each mL of Isophane suspension contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack : 1.5 ml & 3ml Cartridges & Penfills & Prefilled Syringes



Joint Commissioner (H.Q.)
 Food and Drugs Administration
 Maharashtra State, Mumbai

174	WOSULIN - N 100 IU/mL Insulina Humana Isofana (Recombinant DNA Origin) Suspension for Injection NPH- Monocomponent Insulin (Human)	Each mL contains : Human Insulin (recombinant) 100 IU* Excipients : Disodium Hydrogen phosphate anhydrous,Glycerin,Zinc (as Zinc Oxide),m-Cresol,Phenol,Protamine Sulphate,Sodium Hydroxide,Hydrochloric Acid,Water for Injection qs Pack : 10 mL, 5 mL, 3 mL Vial & 3 mL Cartridge *Containing 2.5% overages
175	WOSULIN - N 100 IU/mL Isophane Insulin Human Suspension USP Recombinant DNA origin, Monocomponent Insulin- NPH, Suspension for Injection	Each mL of Isophane suspension contains: Insulin Human USP 100 IU Phenol USP (as preservative) 0.065 % w/v m-Cresol USP (as preservative) 0.16 % w/v Water for Injection USP qs Pack : 10 mL, 5 mL Vial
176	WOSULIN - N 40 IU / mL Isophane Insulin Human Suspension USP Recombinant DNA origin, Monocomponent Insulin- NPH, Suspension for Injection	Each mL of Isophane suspension contains: Insulin Human USP 40 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack : 10 mL Vial

... [17](#) [18](#) [19](#) [20](#) [21](#) [22](#) [23](#) [24](#) [25](#) [26](#)

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**

Food & Drug Administration, M.S.

Bandra (E), Mumbai.

Maharashtra State, India

Date:11 Aug 2025



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427 **VALID UPTO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
177	WOSULIN - R 100 IU / mL Insulin Human Injection USP, Human Recombinant (r-DNA) Insulin, Regular (Soluble/Neutral), Solution for Injection	Each mL contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack : 1.5 ml & 3ml Cartridges & Penfills & Prefilled Syringes
178	WOSULIN - R 100 IU/mL Insulin Human Injection USP, Human Recombinant (r-DNA) Insulin, Regular (Soluble/Neutral),Solution for Injection.	Each ml contains : Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack : 10 mL Vial
179	WOSULIN - R 100 IU/mL Insulina Humana (Recombinant DNA Origin) Injection Solution Regular Monocomponent Insulin (Human)	Each mL contains : Human Insulin (recombinant) 100 IU* Excipients: Zinc (as Zinc Oxide), m-Cresol, Glycerin, Citric Acid monohydrate, Trisodium Citrate Dihydrate, Sodium Hydroxide, Hydrochloric Acid, Water for Injection qs *Containing 2.5% overages Pack : 10 mL Vial , 5 mL Vial & 3 mL Vial & 3 mL cartridge
180	WOSULIN - R 40 IU/mL Insulin Human Injection USP, Human Recombinant (r-DNA) Insulin, Regular (Soluble/Neutral), Solution for Injection	Each mL contains: Insulin Human USP 40 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack : 10 mL Vial
181	WOSULIN N Isophane Insulin Human (Recombinant DNA Origin) 100IU/mL Suspension for Injection	Each mL Contains Human Insulin USP 100 IU m-Cresol (as Preservatives) 0.16 % w/v Phenol (as Preservatives) 0.065 % w/v Water for Injection QS Pack: 10 ml Vial
182	WOSULIN N - DISPOPEN Isophane Insulin Human Suspension USP (Recombinant DNA Origin) NPH - Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Isophane Insulin Human Suspension USP 100 IU/mL. Each ml contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.
183	Wosulin N 100 IU/mL Isophane Insulin Injection IP 100IU/mL, (Recombinant DNA origin), NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Human Insulin IP 100 IU m-Cresol USP 0.16 % w/v (as preservative) Phenol IP 0.065 % w/v (as preservative) Water for Injections IP qs Pack: 3 ml Cartridge




Joint Commissioner (H.Q.)
Food and Drugs Administration
Maharashtra State, Mumbai

184	Wosulin N 100 IU/mL Isophane Insulin Injection IP 100IU/mL, (Recombinant DNA origin), NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Human Insulin IP 100 IU m-Cresol USP 0.16 % w/v (as preservative) Phenol IP 0.065 % w/v (as preservative) Water for Injections IP qs Pack: 10 ml Vial
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... [17](#) [18](#) [19](#) [20](#) [21](#) [22](#) [23](#) [24](#) [25](#) [26](#)

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO- GMP/CERT/AD/150740/2025/11/56427 **VALID UPTO :10 Aug 2028**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
185	Wosulin N 40 IU/mL Isophane Insulin Injection IP 40IU/mL, (Recombinant DNA origin), NPH-Monocomponent Insulin Human	Each mL of Isophane suspension contains: Human Insulin IP 40 IU m-Cresol USP 0.16 % w/v (as preservative) Phenol IP 0.065 % w/v (as preservative) Water for Injections IP qs Pack: 10 ml Vial
186	WOSULIN R Regular Insulin Human (Recombinant DNA Origin) 100 IU/mL Solution for Injection	Each mL contains: Human Insulin USP 100 IU m-Cresol 0.25% w/v (as Preservatives) Water for Injection QS Pack: 10 ml Vial
187	Wosulin R 100 IU/mL Insulin Injection IP 100 IU/mL, (Recombinant DNA origin), (Regular/Neutral), Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injections IP qs Pack: 10 ml vial
188	Wosulin R 100 IU/mL Insulin Injection IP 100 IU/mL, (Recombinant DNA origin), (Regular/Neutral), Monocomponent Insulin Human	Each mL contains: Human Insulin IP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injections IP qs Pack: 3 ml Cartridge
189	Wosulin R 40 IU/mL Insulin Injection IP 40 IU/mL, (Recombinant DNA origin), (Regular/Neutral), Monocomponent Insulin Human	Each mL contains: Human Insulin IP 40 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injections IP qs Pack: 10 ml vial
190	WOSULIN-30/70 DISOPEN Biphasic Isophane Insulin Injection BP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Biphasic Isophane Insulin Injection BP 100 IU/mL. Each ml contains: Insulin Human USP 100 IU (30% Soluble Insulin Injection & 70% Isophane Insulin Injection) m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.
191	WOSULIN-50/50 DISOPEN Biphasic Isophane Insulin Injection BP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Biphasic Isophane Insulin Injection BP 100 IU/mL. Each mL contains: Insulin Human (50% soluble insulin injection and 50% isophane insulin injection) USP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.



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Maharashtra State, Mumbai

192	WOSULIN-70/30 Insulina Bifasica 100 IU/mL, 70% of Isophane Insulin and 30% of Regular Human Insulin of recombinant DNA Origin Injectable suspension	One 3 mL cartridge contains: 300 IU of biphasic Insulin of recombinant DNA Origin. Pack: 3 ml Cartridge.
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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 11 Aug 2025



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

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BIOTECH PARK, H-14/2, MIDC WALUJ
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
193	WOSULIN-70/30 Insulina Bifasica 100 IU/mL, 70% of Isophane Insulin and 30% of Regular Human Insulin of recombinant DNA Origin Injectable suspension	One 10 mL vial contains; 1000 IU of biphasic Insulin of recombinant DNA Origin. Pack: 10 ml vial.
194	WOSULIN-N Insulina Isofana 100 IU/mL Isophane Insulin of recombinant DNA Origin Injectable suspension	One 10 mL vial contains; 1000 IU of Isophane Insulin of recombinant DNA Origin. Pack: 10 ml vial.
195	WOSULIN-N Insulina Isofana 100 IU/mL Isophane Insulin of recombinant DNA Origin Injectable suspension	One 3 mL cartridge contains: 300 IU of Isophane Insulin of recombinant DNA Origin. Pack: 3 ml Cartridge.
196	WOSULIN-N DISPOPEN Isophane Insulin Human Suspension USP (Recombinant DNA Origin) NPH - Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Isophane Insulin Human Suspension USP 100 IU/mL. Each ml contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.
197	WOSULIN-R Insulina Humana 100 IU/mL Regular Human Insulin of recombinant DNA Origin Injectable solution	One 3 mL cartridge contains; 300 IU of Regular Human Insulin of recombinant DNA Origin. Pack: 3 ml Cartridge.
198	WOSULIN-R Insulina Humana 100 IU/mL Regular Human Insulin of recombinant DNA Origin. Injectable solution	One 10 mL vial contains; 1000 IU of Regular Human Insulin of recombinant DNA origin. Pack: 10 ml vial.
199	WOSULIN-R DISPOPEN Insulin Human Injection USP (Recombinant DNA Origin) Regular (Soluble / Neutral) Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Insulin Human Injection USP 100 IU/mL. Each ml contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge
200	WOZULIM - 30/70 Dispopen Biphasic Isophane Insulin Injection BP (Recombinant DNA Origin) Monocomponent Insulin (Human) 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Biphasic Isophane Insulin Injection BP 100 IU/ml. Each ml contains: Insulin Human USP 100 IU (30% Insulin Human Neutral & 70% Isophane Insulin) m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.

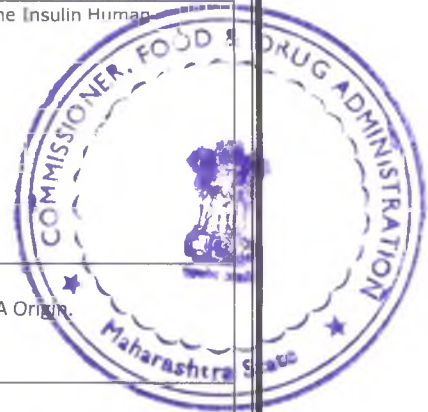
... 17 18 19 20 21 22 23 24 25 26

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Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:11 Aug 2025



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MAHARASHTRA STATE, INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
201	WOZULIM - N 100 IU/mL Isophane Insulin Human suspension USP Recombinant DNA origin. Monocomponent Insulin-NPH	Each mL of Isophane suspension contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.16 % w/v Phenol USP (as preservative) 0.065 % w/v Water for Injection USP qs Pack: 10 ml, 5 ml, 3 ml vial 1.5 ml & 3 ml Cartridge, & Penfills & Pre filled syringes.
202	WOZULIM - N Dispopen Isophane Insulin Human Suspension USP (Recombinant DNA Origin) Monocomponent Insulin - NPH 100 IU/mL	Each Dispopen contains one 3 mL cartridge of Isophane Insulin Human Suspension USP 100 IU/mL. Each ml contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.16 % w/v Phenol (as preservative) USP 0.065 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.
203	WOZULIM - N Insulina Humana Human Suspension USP (Recombinant DNA) 100 IU/mL, Injectable	Each mL contains: Insulin Human USP 100 IU Vehicle qs to 1 ml Pack: 10 ml vial.
204	WOZULIM - R 100 IU/mL Insulin Human Injection USP Human Recombinant (r-DNA) Insulin Regular (Soluble/Neutral)	Each mL contains: Insulin Human USP 100 IU m-Cresol USP (as preservative) 0.25 % w/v Water for Injection USP qs Pack: 10 ml vial, 5 ml vial and 3 ml vial. 1.5 ml & 3 ml Cartridge, & Penfills & Pre filled syringes.
205	WOZULIM - R Dispopen Insulin Human Injection USP Human Recombinant (rDNA)Insulin Regular (Soluble/Neutral)100 IU/mL	Each Dispopen contains one 3 mL cartridge of Insulin Human Injection USP 100 IU/mL. Each ml contains: Insulin Human USP 100 IU m-Cresol (as preservative) USP 0.25 % w/v Water for Injection USP qs Pack: Dispopen containing 3 ml cartridge.




Joint Commissioner (H.Q.)
Food and Drugs Administration,
Maharashtra State, Mumbai

206	Wozulim 30/70 Insulin Injection,Biphasic Isophane Ph.Eur.100 IU/mL	Each mL contains : Insulin Human,Ph.Eur 100 IU (30% Soluble Insulin Injection and 70 % Isophane Insulin Injection) m-Cresol Ph.Eur 0.16% w/v (as preservative) Phenol Ph.Eur. 0.065 % w/v (as preservative) Water for Injection Ph.Eur. ... Quality Sufficient Subcutaneous use only Pack : 10 mL Vial, 3 mL cartridge,3 mL Dispopen - 2 (1 Pre - Filled pen of 3 mL Cartridge) Human Insulin of Recombinant DNA Origin (Biphasic)
207	Wozulim N Insulin Injection Isophane Ph.Eur.100 IU/mL	Each mL contains : Insulin Human Ph.Eur 100 IU m-Cresol Ph.Eur. ... 0.16 % w/v (as preservative) Phenol Ph.Eur. ... 0.065 % w/v (as preservative) Water for Injection Ph.Eur qs For Subcutaneous use Pack : 10 mL Vial, 3 mL Cartridge,3 mL Dispopen - 2 (1 Pre - Filled pen of 3 mL Cartridge) Human Insulin of r-DNA Origin (NPH)
208	Wozulim R Insulin Injection,Soluble Ph.Eur.100 IU/mL	Each mL contains: Insulin Human Ph.Eur 100 IU m-Cresol Ph.Eur. ... 0.25% w/v (as preservative) Water for Injection Ph.Eur. ... Quality Sufficient SC,IV for 10 mL Vial, SC for 3 mL Cartridge and 3 mL Dispopen-2 (1 Pre-filled pen of 3mL Cartridge) Pack : 10 mL Vial, 3 mL Cartridge,3 mL Dispopen - 2 (1 Pre - Filled pen of 3 mL Cartridge) Human Insulin of Recombinant DNA Origin (Regular / Soluble / Neutral)

... 17 18 19 20 21 22 23 24 25 26

Address of certifying authority :
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Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51715074020250811
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/150740/2025/11/56427

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:11 Aug 2025



AUTHORIZATION/MS: 1006398 - REGISTRATION(S): 5070075/22-5
CERTIFICATE OF GOOD MANUFACTURING PRACTICES OF MEDICINES: Sterile products
(Bulk): Lyophilized Powders
.....
MANUFACTURING COMPANY: ALMAC PHARMA SERVICES LIMITED
ADDRESS: SEAGOE INDUSTRIAL ESTATE, PORTADOWN, CRAIGAVON, BT63 5UA - COUNTRY: UNITED KINGDOM - UNIQUE CODE: A.000027
APPLICANT COMPANY: VERTEX FARMACEUTICA DO BRASIL LTDA. - CNPJ: 21.798.065/0001- 02
.....
AUTHORIZATION/MS: 1138239 - FILE(S): 4866787/22-8
CERTIFICATE OF GOOD MANUFACTURING PRACTICES OF MEDICINES: Non-sterile solids: Coated Tablets; Sprinkles
.....
MANUFACTURING COMPANY: DELPHARM MILANO SRL
Address: via Carnevale, 1 - 20054, Segrate, (Mi) - Country: Italy - Single Code: A .000532 Requesting Company: Roche
Chemicals and Pharmacists SA - CNPJ: 33.009.945/0001-23 Authoriz/MS: 1001004 - RECORD(S): 5029111/22-1
CERTIFICATE OF
GOOD MANUFACTURING PRACTICES OF MEDICINES: Non-sterile solids: Capsules; Pills; Coated Tablets
.....
MANUFACTURING COMPANY: ONCOMED MANUFACTURING AS
ADDRESS: KARÁSEK 2229/1B - 621 00 - COUNTRY: CZECH, REPUBLIC - UNIQUE CODE: A .001364
.....
REQUESTING COMPANY: CIPLA BRASIL IMPORTADORA E DISTRIBUIDORA DE MEDICAMENTOS LTDA - CNPJ: 18.268.051/0001-64
AUTHORIZATION/MS: 1115411 - SCHEDULE (s): 0402341/23-6
CERTIFICATE OF GOOD MANUFACTURING PRACTICES OF MEDICINES: Sterile Products (Bulk): Lyophilized Powders
.....
EMPRESA FABRICANTE: AGILERA PHARMA AS
ADDRESS: INSTITUTTVEIEN 18, NO-2007, KJELLER - COUNTRY: NORWAY - UNIQUE CODE: A .000947
APPLICANT
COMPANY: BAYER SA - CNPJ: 18.459.628/0001-15 AUTHORIZATION/MS: 1070568 - REGISTRATION(S): 0469653/2 3 -0 CERTIFICATE OF
GOOD MANUFACTURING PRACTICES OF DRUG PRODUCTS: Sterile Products (Radiopharmaceuticals) (PARAMETRIC RELEASE): Small Volume Parenteral Solutions with Terminal Sterilization
.....
MANUFACTURING COMPANY: TAKEDA IRELAND LIMITED
ADDRESS: BRAY BUSINESS PARK, KILRUDDERY, BRAY, CO. WICKLOW - COUNTRY: IRELAND - UNIQUE CODE: A.000707
REQUESTING COMPANY: PINT PHARMA PRODUTOS MEDICO-HOSPITALARES E FARMACEU TI CO S LTDA - CNPJ: 21.896.000/0001-91
AUTHORIZATION/MS: 1139004 - REGISTRATION(S): 2655671/
22-8 CERTIFICATE OF GOOD MANUFACTURING PRACTICES OF DRUG PRODUCTS: Non-sterile solids: Coated Tablets

RESOLUTION-RE No. 2.266, OF JUNE 22, 2023

The General Manager of Sanitary Inspection and Surveillance, in the use of the attributions conferred by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021; Considering compliance with Good Distribution Practices requirements and/or Storage recommended in current legislation, for the Medicines area, resolves:
Art. 1st Grant to the company(ies) listed in the ANNEX, the Certification of Good Practices for Distribution and/or Storage of Medicines.
Art. 2nd This Certification will be valid for 4 (four) years from its publication.

Art. 3º This Resolution enters into force on the date of its publication.

MARCUS AURÉLIO MIRANDA DE ARAÚJO

ATTACHMENT

COMPANY: VTMED INDUSTRIA E COMERCIO DE MATERIAL MEDICO LTDA - CNPJ: 06.067.548/0001-35 - AUTHORIZATION/MS: 1261652
ADDRESS: RUA FRANCISCO AMORIM Nº 14 - QD 75 CJ CN ET 1
MUNICIPALITY: MANAUS - UF: AM - FILE: 1143457/22-6 CERTIFICATE OF GOOD DISTRIBUTION PRACTICES E/ OR STORAGE: Medicines
.....
COMPANY: HEALTH CARE MED DISTRIBUIDORA LTDA - CNPJ: 41.109.944/0001-89 - AUTHORIZATION/MS: 1286592 ADDRESS: RUA DO IPIRANGA Nº 56 - SALA 112 MUNICIPALITY: CAMPOS DOS GOYTACAZES - UF: RJ - FILE: 0297415/23- 9 CERTIFICATE OF GOOD DISTRIBUTION AND/OR STORAGE PRACTICES: Medicines
.....
COMPANY: GREEN FARMACEUTICA LTDA EPP - CNPJ: 03.411.908/0001-86 - AUTHORIZATION/MS: 1121971 - AE: 1121998 ADDRESS: R BARAO DO RIO BRANCO, 4677 MUNICIPALITY: TOLEDO - UF: PR - FILE: 0446208/23- 0 CERTIFICATE OF GOOD DISTRIBUTION AND/OR STORAGE PRACTICES: Medicines
.....
COMPANY: DISFARMA SAUDE LTDA - CNPJ: 38.159.600/0001-70 - AUTHORIZATION/MS: 1249835 - AE: 1249821
ADDRESS: RUA CORONEL ELPIDIO N 231
MUNICIPALITY: PAULISTANA - UF: PI - REGISTRATION: 0570544/23-8
CERTIFICATE ADO DE BOAS DISTRIBUTION AND/OR STORAGE PRACTICES: Medicines
.....
COMPANY: VIVA FARMACEUTICA SA - CNPJ: 10.447.355/0001-87 - AUTHORIZATION/MS: 1099158 - AE: 1236005
ADDRESS: AV. DOM PEDRO II 3.973 ROOM 702
MUNICIPALITY: BELO HORIZONTE - State: MG - FILE: 0601934/23-7 CERTIFICATE OF GOOD DISTRIBUTION AND/OR STORAGE PRACTICES: Medicines

RESOLUTION-RE No. 2.267, OF JUNE 22, 2023

The General Manager of Sanitary Inspection and Surveillance, in the use of the attributions conferred by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021;
Considering the need to change the Certification of Good Practices of Manufacture, solve:
Art. 1º Change the corporate name of the company GREEN CROSS CORPORATION (Unique code: A.000287) to GC BIOPHARMA CORP., in all certifications in force on June 26, 2023.

Art. 2 This Resolution enters into force on the date of its publication.

MARCUS AURÉLIO MIRANDA DE ARAÚJO

RESOLUTION-RE No. 2.268, OF JUNE 22, 2023

The General Manager of Sanitary Inspection and Surveillance, in the use of the attributions conferred by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021;
Considering compliance with the requirements set out in art. 39, da Collegiate Board Resolution - RDC No. 497, of May 20, 2021, resolves:
Art. 1st Grant to the company(ies) listed in the ANNEX, the Certification of Good Manufacturing Practices for Active Pharmaceutical Ingredients through its automatic renewal.

Art. 2nd This Certification is valid for 2 (two) years from its publication.

Art. 3 This Resolution comes into force on the date of its publication.

MARCUS AURÉLIO MIRANDA DE ARAÚJO

ATTACHMENT

Fabricante: Dr. Reddy's Laboratories Limited - (Chemical Technical Operations - Unit VI)

Address: APIIC Industrial State, Pydibhimavaram (Village), Ranasthalam Mandal, Srikakulam District, Andhra Pradesh - 532409 Country: India Single code: B.000202
File(s): 5110591/22-9 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients : Active pharmaceutical ingredients obtained by chemical synthesis: glatiramer acetate; lurasidone hydrochloride; naratriptan hydrochloride; pioglitazone hydrochloride; sertraline hydrochloride; decitabine; sodium divalproex; sodium ibandronate monohydrate; lenalidomide; levetiracetam; linagliptin; asenapine maleate; mirabegron; oxalate of escitalopram; rivaroxaban; sodium sugammadex; ticagrelor; valsartan; dabigatran etexilate mesylate; quetiapine hemifumarate; voriconazole.

Active pharmaceutical ingredients obtained by chemical synthesis (cytotoxic class): enzalutamide; bendamustine hydrochloride; capecitabine; dasatinib (S)-propylene glycol.

Manufacturer: Janssen Pharmaceutical Sciences Unlimited Company Address: Little Island Industrial Estate, Little Island, Cork- T45 P663 Country: Ireland Single Code: B.000326
File(s): 4935010/22-3 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients : Active pharmaceutical ingredients obtained by chemical synthesis: miconazole; rilpivirine; rilpivirine hydrochloride.

RESOLUTION-RE No. 2.269, OF JUNE 22, 2023

The General Manager of Sanitary Inspection and Surveillance, in the use of the attributions conferred by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021;
Considering compliance with the requirements of Good Manufacturing Practices recommended in current legislation, for the area of Pharmaceutical Inputs, resolves:
Art. 1st Grant to the company(ies) listed in the annex, the Good Manufacturing Practices for Active Pharmaceutical Ingredients.
Art. 2nd This Certification is valid for 2 (two) years from its publication.

Art. 3 This Resolution comes into force on the date of its publication.

MARCUS AURÉLIO DE MIRANDA DE ARAÚJO

ATTACHMENT

Company: Abbott Laboratories of Brazil Ltda. CNPJ: 56.998.701/0012-79 Address: Estrada dos Bandeirantes, nº 2400 Jacarepaguá Municipality: Rio de Janeiro State: RJ
File(s): 5085918/22-3 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Biological Active Pharmaceutical Ingredients: collagenase.

Fabricante: Abbvie Biotechnology Ltd.
Address: Road No. 2, km. 59.2, Barceloneta, PR 00617 Country: Puerto Rico (United States) Single Code: A.000003 Requestor: Takeda Pharma Ltda. CNPJ: 60.397.775/0001-74 File(s): 5013137/22-5 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Biological active pharmaceutical ingredients: vedolizumab.

Manufacturer: Patheon Biologics LLC
Address: 4766 LaGuardia Drive, Saint Louis, Missouri (MO) 63134-3116 Country: United States of America Single Code: A.000146 Requestor: Astellas Farma Brasil Importação e Distribuição de Medicamentos Ltda. CNPJ: 07.768.134/0001-04 File(s): 0402166/23-0 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Biological active pharmaceutical ingredients: zolbetuximab.

Manufacturer: Wockhardt Limited
Address: Biotech Park, H-14/2A, MIDC Waluj, Aurangabad 431136, Maharashtra State Country: India Single Code: A.000631 Requestor: General, Trade and Import of Medical Materials and Equipment Ltd CNPJ: 04.491.780 /0001-70 File(s): 5044488/22-4 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Biological active pharmaceutical ingredients: human insulin.

Manufacturer: WuXi Biologics Co., Ltd.
Address: 108 Meiliang Road, Mashan, Binhu District, Wuxi, 214092 Country: People's Republic of China Single Code: A.001435 Requestor: Brainfarma Indústria Química e Farmacêutica SA CNPJ: 05.161.069/0001-10 File(s): 0498788/ 23-7 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Biological active pharmaceutical ingredients: Antigen suspension for COVID-19 vaccine (recombinant, adjuvant).

RESOLUTION-RE No. 2.270, OF JUNE 22, 2023

The General Manager of Sanitary Inspection and Surveillance, in the use of the attributions conferred by art. 140, combined with art. 203, I, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021;
Considering compliance with the requirements of Good Manufacturing Practices recommended in current legislation, for the area of Pharmaceutical Inputs, resolves:
Art. 1st Grant to the company(ies) listed in the annex, the Good Manufacturing Practices for Active Pharmaceutical Ingredients.
Art. 2nd This Certification is valid for 2 (two) years from its publication.

Art. 3 This Resolution comes into force on the date of its publication.

MARCUS AURÉLIO MIRANDA DE ARAÚJO

ATTACHMENT

Fabricante: Dr. Reddy's Laboratories Limited (Chemical Technical Operations - Unit V)
Address: Peddadevulapalli, Tripuraram Mandal, Nalgonda District, Telangana - 508207 Country: India Single code: B.000338 File(s): 0024633/23-2
Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Active pharmaceutical ingredients obtained by chemical synthesis : pregabalin, ondansetron, ondansetron hydrochloride dihydrate, rabeprazole sodium and montelukast sodium.

Fabricante: Dr. Reddy's Laboratories Ltd (Cto-SEZ Process Unit-01)





Resolución No. 2022500939 DEL 18 DE ABRIL DE 2022
Por la cual se concede la Renovación de la Certificación de Buenas Prácticas de Manufactura Farmacéutica a WOCKHARDT LIMITED., con número de identidad Corporativa 11-120720

El Director Técnico de Medicamentos y Productos Biológicos del Instituto Nacional de Vigilancia de Medicamentos y Alimentos, Invima, en ejercicio de las facultades conferidas en el Decreto 549 de 2001 y Decreto 2078 de 2012, Ley 1437 de 2011, delegado por Resolución Nro. 2012030788 del 19 de octubre de 2012; y teniendo en cuenta los siguientes.

ANTECEDENTES

Que mediante Resolución No. 2018025105 del 15/06/2018, el Invima concedió la certificación de Buenas Prácticas de Manufactura Farmacéutica a **WOCKHARDT LIMITED**, ubicado en Biotech Park H14/2, MIDC, Waluj, Aurangabad, 431136, Maharashtra State India, **PARA LA FABRICACIÓN DE PRODUCTOS BIOLÓGICOS** con los principios activos y las formas farmacéuticas que se relacionan a continuación:

ESTERILES		
PRINCIPIOS ACTIVOS	FORMAS FARMACEUTICAS	
PRODUCTO BIOLÓGICO: (Origen: Recombinante en levadura) Insulina Humana Regular	Líquidos	Soluciones parenterales de pequeño volumen en viales y carpules
PRODUCTO BIOLÓGICO: (Origen: Recombinante en levadura) Insulina Humana Isofana	Líquidos	Soluciones parenterales de pequeño volumen en viales y carpules
PRODUCTOS BIOLÓGICOS: (De Origen de Recombinante en E. Coli) Insulina Glargina	Líquidos	Soluciones parenterales de pequeño volumen en viales y carpules

NOTAS ACLARATORIAS:

1. Los productos biológicos requieren áreas especiales para su elaboración, entendiéndose por tal, instalaciones físicas independientes de otras áreas de producción, incluidos equipos, sistemas y manejo de aire independiente, esclusas, acceso de personal y de materiales independientes, manejo de vestimenta y entrenamiento apropiado que incluya normas, procedimientos y precauciones a tomar para el personal que ingresa en dichas áreas, con el fin de evitar riesgos de contaminación desde y hacia dichas áreas.
2. Las soluciones y suspensiones estériles son esterilizadas por filtración esterilizante con posterior llenado aséptico.
3. El empaque secundario de los carpules o cartuchos en algunos casos puede ser en forma de esfero para inyección.
4. Los productos Biológicos requieren cadena de frío (2°C - 8° C).
5. El anterior concepto técnico, autoriza únicamente la fabricación de los principios activos y producto terminado con los principios activos y las formas farmacéuticas anteriormente descritas.
6. Cualquier modificación que se haga en las condiciones evaluadas y certificadas durante la presente auditoria, respecto a equipos, áreas, procesos productivos, personal técnico principal o de las empresas con las que se contrató la realización de actividades críticas de producción y control de calidad, deberán ser notificadas al INVIMA con el fin de que éste evalúe y verifique si se requiere una visita de ampliación o verificación del concepto técnico emitido, de acuerdo con las disposiciones de la Normatividad Sanitaria correspondiente, so pena de las acciones a que haya lugar.

Que mediante radicado Nro. 20211091514 de 11/05/2021, la doctora Rubby Aristizábal en calidad de Apoderada de la empresa WOCKHARDT LIMITED, solicitó visita tendiente a la renovación de la certificación en Buenas Prácticas de Manufactura farmacéutica para **WOCKHARDT LIMITED**, ubicado en Biotech Park H14/2, MIDC, waluj, Aurangabad 431136, Maharashtra State India,, para lo cual anexó entre otros documentos: la guía de Inspección de Laboratorios o Establecimientos de Producción Farmacéutica debidamente diligenciada, el expediente maestro del sitio y el soporte del pago electrónico de tarifa 400612 con Nro. de transacción 979305735 del BANCO BBVA COLOMBIA S.A., por concepto de pago de los derechos de la visita.

ASS-AYC-FM025 – V05 – 2018-05-02

Instituto Nacional de Vigilancia de Medicamentos y Alimentos – Invima
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Resolución No. 2022500939 DEL 18 DE ABRIL DE 2022

Por la cual se concede la Renovación de la Certificación de Buenas Prácticas de Manufactura Farmacéutica a WOCKHARDT LIMITED., con número de identidad Corporativa 11-120720

Que los días 4, 5, 6, 7 y 8 de abril de 2022, profesionales de la Dirección de Medicamentos y Productos Biológicos del INVIMA realizaron visita tendiente a la renovación de la certificación de las Buenas Prácticas de Manufactura Farmacéutica en el establecimiento **WOCKHARDT LIMITED**, ubicado en Biotech Park MIDC, H14/2, Waluj, Aurangabad, 431136, Maharashtra State India, emitiendo el siguiente concepto técnico: *“Una vez evaluado el cumplimiento de los requerimientos previstos en la Serie de Informes Técnicos de la OMS Serie 823, Informe Técnico 32: Buenas Prácticas de Manufactura para Productos Farmacéuticos, adoptado por Resolución 03183 de agosto de 1995, Decreto 549 de marzo de 2001, Guía de Inspección de Laboratorios o Establecimientos de Producción Farmacéutica, adoptada por Resolución 1087 de julio de 2001, Resolución 3028 de agosto de 2008 y Decreto 2086 de junio de 2010 del Ministerio de la Protección Social, el grupo de inspección del Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, adscrito al Ministerio de Salud y Protección Social de la República de Colombia, conceptúa que **WOCKHARDT LIMITED**, ubicado en Biotech Park, MIDC, H14/2, Waluj, Aurangabad 431136, Maharashtra State, India, **CUMPLE** con las **BUENAS PRÁCTICAS DE MANUFACTURA PARA PRODUCTOS BIOLÓGICOS**, por lo tanto se **RENUUEVA** el concepto técnico **PARA LA FABRICACIÓN DE LOS PRINCIPIOS ACTIVOS Y PRODUCTOS TERMINADOS**, en las formas farmacéuticas que se relacionan a continuación:*

ESTÉRILES		
PRINCIPIOS ACTIVOS	FORMAS FARMACÉUTICAS	
PRODUCTO BIOLÓGICO (Origen: Recombinante en Levadura: Hansenulla polymorpha): Insulina humana Regular	Líquidos	Soluciones parenterales de pequeño volumen en viales y cámpules de vidrio.
PRODUCTO BIOLÓGICO (Origen: Recombinante en Levadura: Hansenulla polymorpha): Insulina humana Isofana	Líquidos	Suspensiones parenterales de pequeño volumen en viales y cámpules de vidrio.
PRODUCTOS BIOLÓGICOS (De origen de recombinante en E. Coli): Insulina Glargina	Líquidos	Soluciones parenterales de pequeño volumen en viales y cámpules de vidrio.

NOTAS ACLARATORIAS

- Los productos biológicos requieren áreas especiales para su elaboración, entendiéndose por tal, instalaciones físicas independientes de otras áreas de producción, incluidos equipos, sistemas y manejo de aire independiente, esclusas, acceso de personal y de materiales independientes, manejo de vestimenta y entrenamiento apropiado que incluya normas, procedimientos y precauciones a tomar para el personal que ingresa en dichas áreas, con el fin de evitar riesgos de contaminación desde y hacia dichas áreas.
- Las soluciones y suspensiones estériles son esterilizadas por filtración esterilizante con posterior llenado aséptico.
- El empaque secundario de los cámpules en algunos casos puede ser en forma de “Dispopen” para inyección.
- Los productos biológicos requieren cadena de frío (2°C - 8°C).
- El anterior concepto técnico incluye la fabricación de los principios activos: Recombinante en Levadura (Hansenulla polymorpha): Insulina Humana Regular, Recombinante en Levadura (Hansenulla polymorpha): Insulina humana Isofana, Recombinante en E.Coli: Insulina Glargina
- El anterior concepto técnico, autoriza únicamente la fabricación de los principios activos y producto terminado con los principios activos y las formas farmacéuticas anteriormente descritas que requieren cadena de frío.
- Cualquier modificación que se haga en las condiciones evaluadas y certificadas durante la presente auditoria, respecto a equipos, áreas, procesos productivos, personal técnico principal o de las empresas con las que se contrató la realización de actividades críticas de producción y control de calidad, deberán ser notificadas al INVIMA con el fin de que éste evalúe y verifique si se requiere una visita de ampliación o verificación del concepto técnico emitido, de acuerdo con las disposiciones de la Normatividad Sanitaria correspondiente, so pena de las acciones a que haya lugar.”

ASS-AYC-FM025 – V05 – 2018-05-02

Instituto Nacional de Vigilancia de Medicamentos y Alimentos - Invima
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Resolución No. 2022500939 DEL 18 DE ABRIL DE 2022

Por la cual se concede la Renovación de la Certificación de Buenas Prácticas de Manufactura Farmacéutica a WOCKHARDT LIMITED., con número de identidad Corporativa 11-120720

CONSIDERACIONES

Que el Artículo Primero del Decreto 549 de 2001, establece que los laboratorios fabricantes de medicamentos que se produzcan en el país o se importen, deberán solicitar el certificado de Buenas Prácticas de Manufactura.

Que el Parágrafo Segundo del Artículo Segundo del Decreto 549 de 2001, expresa que, si del resultado de la visita se establece que el laboratorio de medicamentos cumple con las Buenas Prácticas de Manufactura, el INVIMA expedirá el certificado de cumplimiento de BPM.

Que el Artículo Sexto del Decreto 549 de 2001, menciona que le corresponde al INSTITUTO NACIONAL DE VIGILANCIA DE MEDICAMENTOS Y ALIMENTOS INVIMA ó a quien éste delegue expedir el certificado de cumplimiento de Buenas Prácticas de Manufactura mediante resolución.

Que el Artículo Sexto del Decreto 2086 de 2010 que modifica el Artículo Séptimo del Decreto 549 de 2001 en cuanto a la vigencia del certificado de cumplimiento de las Buenas Prácticas de Manufactura, establece que el certificado de cumplimiento de Buenas Prácticas de Manufactura tendrá una vigencia de tres (3) años contados a partir de la fecha de ejecutoria del acto que lo concede.

Que el Parágrafo del Artículo Sexto del Decreto 2086 de 2010 que modifica el Artículo Séptimo del Decreto 549 de 2001, establece que el certificado de cumplimiento de Buenas Prácticas de Manufactura deberá renovarse por un periodo igual al de su vigencia.

Que profesionales de la Dirección de Medicamentos y Productos Biológicos conceptuaron en acta de visita practicada los días 4, 5, 6, 7 y 8 de abril de 2022, que el establecimiento WOCKHARDT LIMITED, ubicado en Biotech Park H14/2, MIDC, waluj, Aurangabad 431136, Maharashtra State India, CUMPLE con las BUENAS PRÁCTICAS DE MANUFACTURA FARMACÉUTICA PARA PRODUCTOS BIOLÓGICOS, en mérito de lo anterior, este despacho,

RESUELVE

ARTÍCULO PRIMERO. - Conceder la **RENOVACIÓN** de la **CERTIFICACIÓN** de cumplimiento de Buenas Prácticas de Manufactura Farmacéutica para Productos Biológicos, por el término de tres (03) años contados a partir de la ejecutoria de la presente Resolución al establecimiento **WOCKHARDT LIMITED**, ubicado en Biotech Park H14/2, MIDC, Waluj, Aurangabad 431136, Maharashtra State, India, **PARA LA FABRICACIÓN DE LOS PRINCIPIOS ACTIVOS Y PRODUCTOS TERMINADOS**, en las formas farmacéuticas que se relacionan a continuación:

ESTÉRILES		
PRINCIPIOS ACTIVOS	FORMAS FARMACÉUTICAS	
PRODUCTO BIOLÓGICO (Origen: Recombinante en Levadura: Hansnulla polymorpha): Insulina humana Regular	Líquidos	Soluciones parenterales de pequeño volumen en viales y cámpules de vidrio.
PRODUCTO BIOLÓGICO (Origen: Recombinante en Levadura: Hansnulla polymorpha): Insulina humana Isofana	Líquidos	Suspensiones parenterales de pequeño volumen en viales y cámpules de vidrio.
PRODUCTOS BIOLÓGICOS (De origen de recombinante en E. Coli): Insulina Glargina	Líquidos	Soluciones parenterales de pequeño volumen en viales y cámpules de vidrio.

NOTAS ACLARATORIAS

1. Los productos biológicos requieren áreas especiales para su elaboración, entendiéndose por tal, instalaciones físicas independientes de otras áreas de producción, incluidos equipos, sistemas y manejo de aire independiente, esclusas, acceso de personal y de materiales independientes, manejo de

ASS-AYC-FM025 – V05 – 2018-05-02

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Resolución No. 2022500939 DEL 18 DE ABRIL DE 2022

Por la cual se concede la Renovación de la Certificación de Buenas Prácticas de Manufactura Farmacéutica a WOCKHARDT LIMITED., con número de identidad Corporativa 11-120720

vestimenta y entrenamiento apropiado que incluya normas, procedimientos y precauciones a tomar para el personal que ingresa en dichas áreas, con el fin de evitar riesgos de contaminación desde y hacia dichas áreas.

2. Las soluciones y suspensiones estériles son esterilizadas por filtración esterilizante con posterior llenado aséptico.
3. El empaque secundario de los cámpules en algunos casos puede ser en forma de "Dispopen" para inyección.
4. Los productos biológicos requieren cadena de frío (2°C - 8°C).
5. El anterior concepto técnico incluye la fabricación de los principios activos: Recombinante en Levadura (Hansenulla polymorpha): Insulina Humana Regular, Recombinante en Levadura (Hansenulla polymorpha): Insulina humana Isofana, Recombinante en E.Coli: Insulina Glargina
6. El anterior concepto técnico, autoriza únicamente la fabricación de los principios activos y producto terminado con los principios activos y las formas farmacéuticas anteriormente descritas que requieren cadena de frío.
7. Cualquier modificación que se haga en las condiciones evaluadas y certificadas durante la presente auditoria, respecto a equipos, áreas, procesos productivos, personal técnico principal o de las empresas con las que se contrató la realización de actividades críticas de producción y control de calidad, deberán ser notificadas al INVIMA con el fin de que éste evalúe y verifique si se requiere una visita de ampliación o verificación del concepto técnico emitido, de acuerdo con las disposiciones de la Normatividad Sanitaria correspondiente, so pena de las acciones a que haya lugar.

ARTÍCULO SEGUNDO. - NOTIFICAR por medios electrónicos, de conformidad con lo previsto en el Artículo 4 del Decreto 491 del 28 de marzo de 2020, al representante legal y/o apoderado de **WOCKHARDT LIMITED**, del contenido de la presente Resolución, advirtiéndole que contra ella procede el recurso de reposición que podrá interponer dentro de los diez (10) días siguientes contados a partir de la notificación de la presente Resolución ante el Director Técnico de Medicamentos y Productos Biológicos del Invima, de conformidad con lo establecido en el Artículo 76 del Código de Procedimiento Administrativo y de lo Contencioso Administrativo, Ley 1437 del 2011. La notificación quedará surtida a partir de la fecha y hora en que el administrado reciba el acto administrativo.

ARTÍCULO TERCERO. - La presente Resolución rige a partir de su ejecutoria.

NOTIFÍQUESE Y CÚMPLASE

GUILLERMO JOSÉ PÉREZ BLANCO

Director Técnico de Medicamentos y Productos Biológicos

Proyectó: F. Cepeda (Biol.) PIP; 12/04/2022, Revisión Técnica: G. Hernández (Q.F.) P/PA, Vo.Bo. E. Neira. Coordinadora GTM UNB
Revisión Legal: E. Téllez (Abogada) EL, Archivo: Exp Nro. 360E.

ASS-AYC-FM025 – V05 – 2018-05-02



T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

İYİ ÜRETİM UYGULAMALARI (GMP) SERTİFİKASI

Sertifika No: 2024-201/1	Sertifika Tarihi: 23.05.2024
Ürün Adı/Adları:	Glaritus Dispopen 100 IU/mL SC Enjeksiyonluk Çözelti İçeren Kullanıma Hazır Enjeksiyon Kalem (3 mL)
Etkin Madde/Maddeler:	İnsulin glarjin
İthalatçı Firma Adı:	Onko İlaç San. ve Tic. A.Ş.
Üretim Tesisi Adı:	Wockhardt Limited
Üretim Tesisi Adresi:	Biotech Park H-14/2 MIDC, Waluj Aurangabad 431136 Maharashtra State, Hindistan
Üretim Tesisinde Gerçekleştirilen Faaliyetler:	Bulk üretim, Primer ambalajlama, Sekonder ambalajlama, Seri serbest bırakma
Denetim Tarihi:	08-11.08.2023

05.10.2023 tarihli ve E-24931227-000-15235 sayılı Makam Oluru ile yürürlüğe giren “Yurt Dışı Üretim Tesislerinin GMP Denetimleri İçin Yapılacak Müracaatlara Dair Kılavuz”un A bendi (yerinde denetim) kapsamında yukarıda adı geçen ürünün bahsi geçen tesiste belirtilen işlem basamaklarının “İyi Üretim Uygulamaları (GMP)” kuralları doğrultusunda yapıldığına dair sertifikadır.

Dr. Asım HOCAOĞLU
Kurum Başkanı



Not: Bu belge 11.08.2026 tarihine kadar ve söz konusu ürünün/ürünlerin varsa ilgili kılavuz çerçevesince denetimi gerekli diğer üretim aşamalarının gerçekleştirildiği tesisler için düzenlenmiş olan GMP belgeleri ile birlikte geçerlidir.

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T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

İYİ ÜRETİM UYGULAMALARI (GMP) SERTİFİKASI

Sertifika No: 2024-203/1	Sertifika Tarihi: 23.05.2024
Ürün Adı/Adları:	Glaritus Dispopen 100 IU/mL SC Enjeksiyonluk Çözelti İçeren Kullanıma Hazır Enjeksiyon Kalem (3 mL)
Etkin Madde/Maddeler:	İnsulin glarjin
İthalatçı Firma Adı:	Onko İlaç San. ve Tic. A.Ş.
Üretim Tesisi Adı:	Wockhardt Limited
Üretim Tesisi Adresi:	Biotech Park H-14/2 A MIDC, Waluj Aurangabad 431136 Maharashtra State, Hindistan
Üretim Tesisinde Gerçekleştirilen Faaliyetler:	Etkin madde üretimi
Denetim Tarihi:	08-11.08.2023

05.10.2023 tarihli ve E-24931227-000-15235 sayılı Makam Oluru ile yürürlüğe giren "Yurt Dışı Üretim Tesislerinin GMP Denetimleri İçin Yapılacak Müracaatlara Dair Kılavuz"un A bendi (yerinde denetim) kapsamında yukarıda adı geçen ürünün bahsi geçen tesiste belirtilen işlem basamaklarının "İyi Üretim Uygulamaları (GMP)" kuralları doğrultusunda yapıldığına dair sertifikadır.

Dr. Asım HOCAOĞLU
Kurum Başkanı



Not: Bu belge 11.08.2026 tarihine kadar ve söz konusu ürünün/ürünlerin varsa ilgili kılavuz çerçevesince denetimi gerekli diğer üretim aşamalarının gerçekleştirildiği tesisler için düzenlenmiş olan GMP belgeleri ile birlikte geçerlidir.



T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

İYİ ÜRETİM UYGULAMALARI (GMP) SERTİFİKASI

Sertifika No: 2024-202/1	Sertifika Tarihi: 23.05.2024
Ürün Adı/Adları:	Glaritus 100 IU/mL SC Kullanım İçin Enjeksiyonluk Çözelti İçeren Kartuş (3 mL)
Etkin Madde/Maddeler:	İnsulin glarjin
İthalatçı Firma Adı:	Onko İlaç San. ve Tic. A.Ş.
Üretim Tesisi Adı:	Wockhardt Limited
Üretim Tesisi Adresi:	Biotech Park H-14/2 A MIDC, Waluj Aurangabad 431136 Maharashtra State, Hindistan
Üretim Tesisinde Gerçekleştirilen Faaliyetler:	Etkin madde üretimi
Denetim Tarihi:	08-11.08.2023

05.10.2023 tarihli ve E-24931227-000-15235 sayılı Makam Oluru ile yürürlüğe giren “Yurt Dışı Üretim Tesislerinin GMP Denetimleri İçin Yapılacak Müracaatlara Dair Kılavuz”un A bendi (yerinde denetim) kapsamında yukarıda adı geçen ürünün bahsi geçen tesiste belirtilen işlem basamaklarının “İyi Üretim Uygulamaları (GMP)” kuralları doğrultusunda yapıldığına dair sertifikadır.

Dr. Asım HOCAOĞLU
Kurum Başkanı



Not: Bu belge 11.08.2026 tarihine kadar ve söz konusu ürünün/ürünlerin varsa ilgili kılavuz çerçevesince denetimi gerekli diğer üretim aşamalarının gerçekleştirildiği tesisler için düzenlenmiş olan GMP belgeleri ile birlikte geçerlidir.



T.C. SAĞLIK BAKANLIĞI
TÜRKİYE İLAÇ VE
TIBBİ CİHAZ KURUMU

İYİ ÜRETİM UYGULAMALARI (GMP) SERTİFİKASI

Sertifika No: 2024-200/1	Sertifika Tarihi: 23.05.2024
Ürün Adı/Adları:	Glaritus 100 IU/mL SC Kullanım İçin Enjeksiyonluk Çözelti İçeren Kartuş (3 mL)
Etkin Madde/Maddeler:	İnsulin glarjin
İthalatçı Firma Adı:	Onko İlaç San. ve Tic. A.Ş.
Üretim Tesisi Adı:	Wockhardt Limited
Üretim Tesisi Adresi:	Biotech Park H-14/2 MIDC, Waluj Aurangabad 431136 Maharashtra State, Hindistan
Üretim Tesisinde Gerçekleştirilen Faaliyetler:	Bulk üretim, Primer ambalajlama, Sekonder ambalajlama, Seri serbest bırakma
Denetim Tarihi:	08-11.08.2023

05.10.2023 tarihli ve E-24931227-000-15235 sayılı Makam Oluru ile yürürlüğe giren “Yurt Dışı Üretim Tesislerinin GMP Denetimleri İçin Yapılacak Müracaatlara Dair Kılavuz”un A bendi (yerinde denetim) kapsamında yukarıda adı geçen ürünün bahsi geçen tesiste belirtilen işlem basamaklarının “İyi Üretim Uygulamaları (GMP)” kuralları doğrultusunda yapıldığına dair sertifikadır.

Dr. Asım HOCAOĞLU
Kurum Başkanı



Not: Bu belge 11.08.2026 tarihine kadar ve söz konusu ürün/ürünlerin varsa ilgili kılavuz çerçevesince denetimi gerekli diğer üretim aşamalarının gerçekleştirildiği tesisler için düzenlenmiş olan GMP belgeleri ile birlikte geçerlidir.

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Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-14 Aug 2024

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.
(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/AD/135878/2024/11/51215**

On the basis of the inspection carried out on **20.05.2024 and 21.05.2024**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **WOCKHARDT LIMITED**
Address : **BIOTECH PARK, H-14/2A, MIDC, WALUJ,
AURANGABAD-431136, MAHARASHTRA, INDIA
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA**
2. Licence No. : **MH102194 In Form
28D**

Table 1

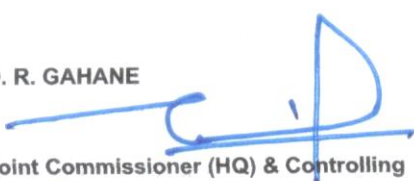
Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	Recombinant Vaccines / Drugs	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 13 Aug 2027 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW04713587820240814
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/135878/2024/11/51215

Name of the Authorised person : **D. R. GAHANE**

Signature : 
Stamp and Date : **Joint Commissioner (HQ) & Controlling
Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 14 Aug 2024**



Explanatory notes

1. This certificate which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.
2. The certification number should be traceable within the regulatory authority issuing the certificate.
3. Where the regulatory authority issues a licence for the site, this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.
4. Table 1
List the dosage forms, starting materials, categories and activities. Examples are given below.

Example -1

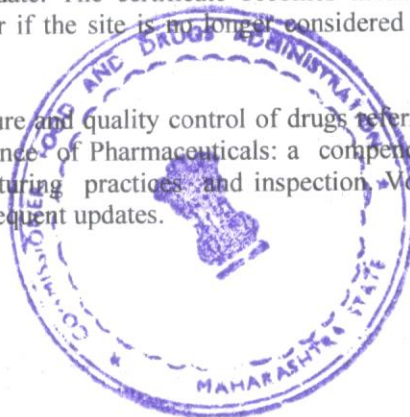
Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Hormone	Production, Packaging, Quality control.
Injectables	Penicillin	Repackaging & Labelling.
	Cefalosporin	Aseptic preparation, Packaging, Labelling.

Example - 2.

Pharmaceutical Product (s)1	Category (ies)	Activity (ies)
Starting material (s)2		
Paracetamol	Analgesic	Synthesis, Purification, Packing, Labelling.

Use, whenever available. International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organization, Geneva and subsequent updates.



LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-
GMP/CERT/AD/135878/2024/11/51215 **VALID UP TO :13 Aug 2027**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2A, MIDC, WALUJ,
AURANGABAD-431136, MAHARASHTRA, INDIA
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : MH102194 In Form 28D

Sr.No.	Name of the Product	Composition
1	Erythropoietin Concentrated Solution BP (Bulk Pack & Export Market)	
2	Erythropoietin Concentrated Solution BP (Bulk Pack and Domestic Market)	
3	Human Insulin BP (Bulk Pack & Domestic Market)	
4	Human Insulin BP (Bulk Pack and Export Market)	
5	Insulin Human Ph.Eur (Bulk Pack & Export Market)	
6	Insulin Human Ph.Eur (Bulk Pack and Domestic Market)	
7	Human Insulin IP (Export Market)	
8	Insulin Glargine (Domestic Market)	

1 2 3

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW04713587820240814
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/135878/2024/11/51215

Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:14 Aug 2024

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-
GMP/CERT/AD/135878/2024/11/51215 **VALID UP TO :13 Aug 2027**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2A, MIDC, WALUJ,
AURANGABAD-431136, MAHARASHTRA, INDIA
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : MH102194 In Form 28D

Sr.No.	Name of the Product	Composition
9	Insulin Glargine BP (Domestic Market)	
10	Insulin Glargine BP (Export Market)	
11	Insulin Glargine USP (Domestic Market)	
12	Insulin Human USP (Export Market)	
13	Erythropoietin Concentrated Solution IP (Domestic Market)	
14	Erythropoietin Concentrated Solution IP (Export Market)	
15	Erythropoietin Concentrated Solution Ph.Eur. (Domestic Market)	
16	Erythropoietin Concentrated Solution Ph.Eur. (Export Market)	

1 2 3

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
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WOCKHARDT LIMITED - NEW-WHO-
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Name of the Authorised person : **D. R. GAHANE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: **14 Aug 2024**

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

VALID UP TO :13 Aug 2027

No. of certificate : NEW-WHO-
GMP/CERT/AD/135878/2024/11/51215

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2A, MIDC, WALUJ,
AURANGABAD-431136, MAHARASHTRA, INDIA
CHHATRAPATI SAMBHAJINAGAR 431136
MAHARASHTRA STATE, INDIA

Drug License No : MH102194 In Form 28D

Sr.No.	Name of the Product	Composition
17	Human Insulin IP (Domestic Market)	
18	Insulin Glargine (Export Market)	
19	Insulin Glargine IP (Domestic Market)	
20	Insulin Glargine IP (Export Market)	
21	Insulin Glargine Ph.Eur. (Domestic Market)	
22	Insulin Glargine Ph.Eur. (Export Market)	
23	Insulin Glargine USP (Export Market)	
24	Insulin Human USP (Domestic Market)	



123

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW04713587820240814
WOCKHARDT LIMITED - NEW-WHO-
GMP/CERT/AD/135878/2024/11/51215

Name of the Authorised person : D. R. GAHANE

Signature:

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 14 Aug 2024



CERTIFICADO DE REGISTRO SANITARIO
Dispositivos Médicos, Materiales Cortopunzantes y Equipo
de Protección Individual

La Dirección Nacional de Vigilancia Sanitaria, autoriza el Registro Sanitario del producto más abajo descrito, cumpliendo la misma con los requisitos y las legislaciones vigentes en la República del Paraguay según Código Sanitario Ley N° 836/80, Ley N° 6788/2021 y demás normativas vigentes.

Certificado N°: **DM-002979-01**

Vencimiento: **09-07-2035**

Denominación Comercial: **MYPEN 2**

Denominación Genérica/Código ECRI: **INYECTORES, PARA MEDICACIÓN/VACUNACIÓN, SIN AGUJA 18-069**

Clase: **CLASE III**

Marca: **MYPEN**

Modelo: **DISPOSITIVO DE ENTREGA DE INSULINA REUTILIZABLE.**

Material de Composición: **1- TAPA DEL PEN- PLÁSTICO PP (POLIPROPILENO)2-CUERPO DEL PEN- PLÁSTICO ABS (ACRILONITRILO BUTADIENO ESTIRENO)3- CUBIERTA IMPRESA DEL CARTUCHO- PLÁSTICO ABS (ACRILONITRILO BUTADIENO ESTIRENO)**

Accesorios: **N/A**

Presentación: **ENVASE PRIMARIO: LAPICERA MYPEN 2 ENVASE SECUNDARIO Y UNIDAD DE VENTA:CAJA CONTENIENDO 1 LAPICERA MYPEN 2 DE INSULINA REUTILIZABLE, 1 INSTRUCCIONES DE USO**

Plazo de Vida Útil: **MYPEN 2 ES VÁLIDO PARA SU USO HASTA 3 AÑOSA PARTIR DE LA FECHA DEL PRIMER USO.**

Condición de Venta: **VENTA BAJO RECETA**

Titular: **FUSA S.A. - ---**

Director Técnico: **ID BARCHELLO SARA CONCEPCIÓN**

Elaborador Producto Final: **BIOTECH PARK, H-14/2, M.I.D.C., WALUJ, 431136., AURANGABAD, MAHARASHTRA, INDIA por WOCKHARDT LIMITED Fabricado para WOCKHARDT LIMITED (BKC TOWER, BANDRA EAST MUMBAI, INDIA)**

Asunción 09 de Julio de 2025.

SANDRA MARIA
VANESSA
BAREIRO DE
OVIEDO

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por SANDRA MARIA
VANESSA BAREIRO DE
OVIEDO
Fecha: 2025.07.09
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گواهی استقرار اصول بهینه تولید
GMP Certificate

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Company Name:	Wockhardt Limited	وکهارد	نام شرکت:
Activity:	Insulin Production	تولید انسولین	فعالیت:
Authorised Person:	Pravir Choubey	پروایر چوبی	مسوول فنی:
Establishment Date:	11-12720	۱۱-۱۲۷۲۰	تاریخ پروانه تاسیس:
Establishment No:	1378/04/17	۱۹۹/۰۷/۰۸	شماره پروانه تاسیس:
Country:	India	هند	کشور:
Address:	H-14/2, M.I.D.C Area, Waluj, Aurangabad-431 136. India	-	نشانی:
Telephone:	+91 240662644	+۹۱ ۲۴۰۶۶۲۶۴۴	تلفن:
Inspected Line:	Insulin API & Finished product	ماده موثره و فرآورده نهائی انسولین	خط بازدید شده:
Inspection Date:	Jun 2012	خرداد ۱۳۹۱	تاریخ بازدید:

بدینوسیله گواهی می‌شود خط تولید ماده موثره و فرآورده نهائی انسولین شرکت فوق مورد بازدید کارشناسی اصول بهینه تولید (GMP) قرار گرفته و باتوجه به شرایط موجود مورد تایید می‌باشد. مدت اعتبار این گواهی از تاریخ صدور به مدت دو سال است.

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice principles for pharmaceutical products which are currently in force in the I.R. of Iran. Therefore, the production of Insulin API & Finished product is in compliance with the cGMP standards and relevant principles and regulations.

This certificate is valid for 2 years from date of issue.

معاون دارویی سازمان غذا و دارو
General Director

MOH Building, No.3, Fakhr-
e-Razi st., Enghelab .
Tehran, IRAN
Tel: (98 21) 66466939
Fax: (98 21) 66469142

PO Box: 13145-719
Postal Code: 1314715311

e-mail: phdu@fdo.ir
Website: www.fdo.ir



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2013, 6, 22



SECRETARÍA DE SALUD

COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

COMISIÓN DE AUTORIZACIÓN SANITARIA

MODIFICACIÓN DEL REGISTRO SANITARIO No.

078M2017 SSA

No. DE SOLICITUD

24330022130852

No. DE SOLICITUD ANTERIOR

24330022130067

Con fundamento en los artículos 4 párrafo cuatro, 8, 14 y 16 de la Constitución Política de los Estados Unidos Mexicanos; 2 fracción I, 14 primer párrafo, 17, 26 fracción XVI, 39 XXI y XXVII de la Ley Orgánica de la Administración Pública Federal; 1, 2, 3, 13, 15, 16, fracción X, 17-A y 31 de la Ley Federal de Procedimiento Administrativo; 1, 4 fracción III, 17 Bis fracción IV, VI y XIII, 194 Bis, 197, 198 fracción II, 221, 222, 222 Bis, 224 inciso B fracción I, 226, 368, 371, 376, 376 bis, 378 y 393 de la Ley General de Salud; 1, 8, 10, 81, 113, 153, 157, 165, 167-bis, 168, 170, 177, 177 Bis 1, 177 Bis 2, 177 Bis 3, 177 Bis 4, 177 Bis 5, 185, 186, 187 y 189 del Reglamento de Insumos para la Salud; 1, 2 inciso C fracción II, 44 y 45 del Reglamento Interior de la Secretaría de Salud; 1, 3 fracción I inciso b), VII y XIII, 4, fracción II, inciso c, 11, fracciones VI y XI, 14, fracciones I y XIV y 21 del Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios; Décimo Quinto del Acuerdo por el que se delegan las facultades que se señalan, en los Órganos Administrativos que en el mismo se indican de la Comisión Federal para la Protección Contra Riesgos Sanitarios, publicado en el Diario Oficial de la Federación el 07 de abril de 2010, se autoriza la **MODIFICACIÓN** a las condiciones de registro sanitario bajo las siguientes condiciones:

Titular:

Wockhardt Limited

Biotech Park, H-14/2, MIDC Waluj Aurangabad 431136 Maharashtra State, India.

CARACTERÍSTICAS DEL PRODUCTO

Denominación Distintiva: VALVEY

Denominación Genérica: Insulina glargina

Clasificación Artículo 226 LGS: IV

Clasificación Artículo 2 RIS: Medicamento biotecnológico biocomparable

Forma Farmacéutica: Solución

Fabricante del Fármaco: Wockhardt Limited
Biotech Park, H-14/2, MIDC Waluj Aurangabad 431136 Maharashtra State, India.

Fabricante del Medicamento: Wockhardt Limited
Biotech Park, H-14/2, MIDC Waluj Aurangabad 431136 Maharashtra State, India.

Wockhardt Limited

E-1/1, Wockhardt Infrastructure Development Ltd, Sez E-1, Shendra MIDC, Five Star Industrial Area,
Shendra Aurangabad 431154, Maharashtra State, India.

Acondicionador:

Primario y secundario:

Wockhardt Limited

Biotech Park, H-14/2, MIDC Waluj Aurangabad 431136 Maharashtra State, India.



Wockhardt Limited

E-1/1, Wockhardt Infrastructure Development Ltd, Sez E-1, Shendra MIDC, Five Star Industrial Area,
Shendra Aurangabad 431154, Maharashtra State, India.

Representante Legal e
Importador:

Medicamentos Internacionales Medinter, S.A. de C.V.

Avenida Empresarios No. 135 Piso 7C, Col. Puerta de Hierro, C.P. 45116, Zapopan, Jalisco, México.

Importador:

Ackerman Pharma, S.A. de C.V.

Avenida Jalisco No. 108 B, Primer Piso, Col. Tacubaya, C.P. 11870, Miguel Hidalgo, Ciudad de México,
México.

Concept G&C International, S.A. de C.V.

Boulevard San Juan Bosco No. 3154, Col. Cañada del Refugio, C.P. 37358, León, Guanajuato, México.

Distribuidor:

Ackerman Pharma, S.A. de C.V.

Cerrada Galeana No. 4, Col. La Loma, C.P. 54060, Tlalnepantla de Baz, México, México.

Gabame, S.A. de C.V.

Avenida Acueducto Del Alto Lerma No. 6, Interior 1 Bodega 10, Centro Ocoyoacac, C.P. 52740,
Ocoyoacac, México, México.

Concept G&C International, S.A. de C.V.

Boulevard San Juan Bosco No. 3154, Col. Cañada del Refugio, C.P. 37358, León, Guanajuato, México.

Unidad de farmacovigilancia:

Medicamentos Internacionales Medinter, S.A. de C.V.

Avenida Empresarios No. 135, 7C, Col. Puerta de Hierro, C.P. 45116, Zapopan, Jalisco, México.

Fecha de expedición:

29 de agosto de 2025

Fecha de vencimiento:

25 de abril de 2027

Presentaciones:

Caja de cartón con un frasco ampula con 10 mL (100 UI/mL).

Caja de cartón con 1 o 5 cartucho(s) con 3 mL (100 UI/mL).

Caja de cartón con 1 o 5 pluma(s) precargada(s) (Valvey® DispoPen) con 3 mL (100 UI/mL).

Todas las presentaciones con instructivo anexo.

Envase para solución:

Frasco ampula de vidrio tipo I

Cartucho de vidrio tipo I

Vida Útil:

24 meses, debiendo expresar el año con número y el mes con letra.

Indicaciones Terapéuticas:

Para el tratamiento de la diabetes mellitus tipo 1 y tipo 2.

Contraindicaciones:

Hipersensibilidad a la insulina glargina o a cualquiera de los componentes de la fórmula, hipoglucemia y
menores de 18 años.

Fórmula

100 UI/mL

Cada mL contiene:

Fármaco

Insulina glargina

100 UI

Análogo de insulina de origen ADN recombinante expresado en



Escherichia coli.

Equivalente a:	3.64 mg	La cantidad en mg se ajusta de acuerdo a la potencia del fármaco y se adiciona un 2% de exceso.
Aditivos		
Zinc	0.030 mg	Se adiciona como cloruro de zinc equivalente a...
Glicerol	20.000 mg	85%
Cresol	2.700 mg	Se destilan 3.26 µL de m-cresol (d=1.03 g/cm3) y del destilado se toman 2.70 mg que se utilizan para la fabricación del medicamento.
Ácido clorhídrico	CS	1 N. Ajuste de pH 2.7 a 3.3
Hidróxido de sodio	CS	1 N. Ajuste de pH 3.9 a 4.2
Agua para la fabricación de inyectables	1.000 mL	cbp

Vía de Administración: Subcutánea
Consideración de uso: Inyectable

Observaciones al Registro:

- Se autoriza como fabricante del medicamento y acondicionador a Wockhardt Limited, con domicilio en "E-1/1, Wockhardt Infrastructure Development Ltd, Sez E-1, Shendra MIDC, Five Star Industrial Area, Shendra Aurangabad 431154, Maharashtra State, India".
- Se autoriza el cambio de domicilio de la Unidad de Farmacovigilancia "Medicamentos Internacionales Medinter, S.A. de C.V.", de "Avenida de la Palma No. 8, Oficina 306, Col. Interlomas, C.P. 52787, Huixquilucan, México, México" a "Avenida Empresarios No. 135, 7C, Col. Puerta de Hierro, C.P. 45116, Zapopan, Jalisco, México".
- Se autorizan marbetes e instructivo anexo conforme a la NOM-072-SSA1-2012, "Etiquetado de medicamentos y de remedios herbolarios", por actualización.
- Se autoriza la Información para Prescribir en su versión Amplia y Reducida, de acuerdo a lo que establece el Artículo 42 del Reglamento de la Ley General de Salud en Materia de Publicidad, por actualización.
- Se actualiza la descripción de la Fórmula con base en la información presentada.
- De conformidad con el Artículo 189 del Reglamento de Insumos para la Salud, se cuenta con un plazo de agote de existencias de hasta 240 días hábiles, el plazo descrito es improrrogable.
- Se hace de su conocimiento, que cuenta con un plazo de diez días hábiles, contados a partir del día siguiente hábil al en que surta la notificación del presente, para someter la petición de Corrección Interna generada en el presente oficio, en su caso, debiendo agregar documentación que estime necesaria, que sustente la petición, cabe decir que, el plazo señalado es improrrogable, con el APERCIBIMIENTO que en caso de no ingresar en tiempo y forma la solicitud en términos de los artículos 28, 32 y 59 de la Ley Federal de Procedimiento Administrativo, su trámite será improcedente.
- Las condiciones sanitarias del producto al que hace referencia la presente autorización podrán ser verificadas en cualquier momento por la autoridad sanitaria, lo anterior de conformidad con los artículos 17 Bis fracciones IV y VI, y 378 de la Ley General de Salud; 1, 2, 13 y 16 fracción II de la Ley Federal de Procedimiento Administrativo 2 fracción III, 218 fracción I. C., 220 fracciones III y VI del Reglamento de Insumos para la Salud.
- El titular del presente Registro Sanitario deberá de mantener vigente el Certificado de Buenas Prácticas de Fabricación durante la vigencia del Registro Sanitario de que se otorga en este acto.

Anexos: 47.

SUFRAGIO EFECTIVO. NO REELECCIÓN
SUBDIRECTORA EJECUTIVA DE FÁRMACOS Y MEDICAMENTOS

LOURDES VILLARREAL DÍAZ

Con fundamento en lo dispuesto por el artículo DÉCIMO QUINTO del Acuerdo por el que se delegan las facultades que se señalan, en los Órganos Administrativos que en el mismo se indican de la Comisión Federal para la Protección contra Riesgos Sanitarios, publicado en el Diario Oficial de la Federación el 7 de abril de 2010.

JCLG / argz / sagc



شهادة هالة حلال JUHF HALAL CERTIFICATE CERTIFICATION PVT. LTD.

رقم شهادة
JUHF-1397-1194

A JUHF CERTIFICATION PVT LTD PROCEDURE, DOCUMENTED IN AN AUDIT REPORT, HAS VERIFIED THAT THE BELOW LISTED PRODUCT(S) ARE COMPLYING WITH THE HALAL REQUIREMENTS IN ACCORDANCE WITH THE ISLAMIC SHARIAH. THE VERIFICATION AND CERTIFICATION HAVE BEEN UNDERTAKEN IN FULL COMPLIANCE WITH GUIDELINES UNDER MENTIONED. THE PRODUCTS BELOW LISTED ARE HALAL.

COMPANY NAME	WOCKHARDT LIMITED
FACTORY ADDRESS	Biotech Park, H-14/2, MIDC, Waluj, Chhatrapati Sambhajnagar, (Aurangabad) - 431 136, Maharashtra, India.
BUSINESS TYPE	Manufacturer
PRODUCT CATEGORY	F - (Pharmaceutical Product) According to MS K - (Production of (Bio) Chemical- Insulin) According to GSO
STANDARD(S)	MS: 2424:2019 GSO: 2055-2:2015

S. NO.	NAME OF THE PRODUCTS	BRAND NAME	CODE/ DESCRIPTION	HALAL ID
1	Insulin Injection, Soluble (E. coli and H. polymorpha)	Wosulin R, Wozulim R, Winsulin R, Vitasulin R, Insulina R, Glysolin R, Colsulin R, Ecosulin R, Insuwok R	306173, 306174, 302797, 302631 and 305108	JUHf-1397-0001
2	Insulin Injection, Isophane (E. coli and H. polymorpha)	Wosulin N, Wozulim N, Insulina N, Wozulin N, Vitasulin N, Glysolin N, Winsulin N, Glinux N, Ecosulin N, Colsulin N, Insuwok N	306172, 306171, 302796, 302630 and 305102	JUHf-1397-0002
3	Insulin Injection, Biphasic Isophane (E. coli and H. polymorpha)	Wosulin 30/70, Glysolin 30/70, Vitasulin 30/70, Winsulin 30/70, Wozulim 30/70, Wosulin 70/30, Ecosulin 30/70, Colsulin 30/70, Wocilog 30/70, Insuwok 30/70	306169, 306170, 302794 and 302628	JUHf-1397-0003
4	Insulin Glargine Injection (E. coli)	Glaritus, Viminova, Ylateq, Glarsulin, Glysolin G, Bioglarigine, GlariSan, Valvey, Glaine, Viminova, Lenglar	302075, 304164, 303692 and 305502	JUHf-1397-0004
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—	—	—	—	—

Initial Date 19.12.2025
Date of Issue 19.12.2025
Date of Expiry 18.12.2028
Surveillance 1st 17.09.2026
Surveillance 2nd 17.09.2027
Re-Certification 17.09.2028



سید اسجد

(MAULANA) SYED ASJAD MADANI
MANAGING DIRECTOR

THIS CERTIFICATE IS STRICTLY NON-TRANSFERABLE & ITS PHOTOCOPY SHALL NOT BE DISPLAYED OUTSIDE THE PREMISE MENTIONED ABOVE. THE AUTHENTICITY OF THIS CERTIFICATE CAN BE VERIFIED BY SCANNING QR CODE OR AT WWW.HALALHIND.COM.. ANY ALTERATION, FORGERY, FALSIFICATION OF THE CONTENT OR MISREPRESENTATION OF THIS CERTIFICATE IS ILLEGAL & OFFENDER SHALL BE PROSECUTED. THE CERTIFICATE WILL REMAIN VALID SUBJECT TO SATISFACTORY SURVEILLANCE AUDITS IF PLANNED.

APPROVED AND RECOGNISED BY:



المركز السعودي للحلال
Saudi Halal Center



JUHf CERTIFICATION PVT. LTD., GROUND FLOOR, KHIDMAT CHARITABLE TRUST, IMAMWADA ROAD, UMERKHADI, CHINCHBUNDER, MUMBAI, MAHARASHTRA- 400009, INDIA.
CELL NO. +91- 9321222774, LAND LINE. +91-22-23735373, EMAIL: CONTACT@HALALHIND.COM WEB: WWW.HALALHIND.COM CIN NO: U74999MH2019TTC331593



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

Manufacturer:
Wockhardt Ltd
Biotech Park, H 14/2, MIDC,
Waluj,
Aurangabad-1431136
Maharashtra,
India

UKRP:
Casus UKRP Ltd
107-111 Fleet Street,
London,
EC4A 2AB,
UK

21st July 2025

Our Ref: **DEU/006/2025/001**

Dear Recipient,

MEDICAL DEVICES REGULATIONS 2002 (as amended)
AUTHORISATION OF SPECIAL USE OF MYPEN®2

I refer to your e-mail dated 12th June 2025 in which you requested special approval to supply the above non-UKCA/CE marked medical devices on the UK Market, on the basis that a duly justified request has been made and this is in the interests of the protection of health. The reasons for the application cited:

“As Owen & Mumford devices are being discontinued Wockhardt UK's (Hypurin) cartridges are not compatible with other devices available on the UK market and Wockhardt UK have requested us to supply this device to meet patient need”.

Based on this confirmation, the Secretary of State acting as the MHRA is satisfied that the request is duly justified, and that it is in the interests of the protection of public health to authorise the supply of the device under regulation 12(5) General MDs, of the Medical Device Regulations 2002, subject to the conditions set out below:

1. This authorisation commences on 21st July 2025 and ends on whichever of the following dates occurs soonest:
 - o 21st January 2026;
 - o the date when the device is UKCA/CE marked; or
 - o the date when sufficient quantities of UKCA/CE marked alternative product is available on the market.

If this authorisation ends on 21st January 2026, and there continues to be a need for a further authorisation, the position will be reviewed by the MHRA and a decision taken on whether it remains in the interests of the protection of health for a further authorisation or an amendment to this authorisation to be made.

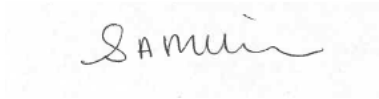
2. That the devices are intended for use in patients who are treated with porcine insulin i.e. the Hypurin® by Wockhardt product only;
3. That the hospitals and/or laboratories in question are supplied with the necessary instructions for use;
4. That you agree to the details of the authorisation being listed on [MHRA's website](#) to confirm the manufacturer and products authorised under this exemption including the issue date and duration.
5. That devices authorised under this exemption are only permitted for sale directly to the NHS and within the health and social care environment. Distributor sales are permitted

however the manufacturer must include within the monthly reports accurate supply data noting the number and components supplied to wholesalers;

6. That you submit to the MHRA a detailed time plan for UKCA/CE marking of the device, or explanation as to why you will not be seeking UKCA/CE marking;
7. That the company submits to the MHRA a monthly report detailing:
 - o supply data (number and components supplied including to which wholesaler;
 - o summary of product complaints;
 - o summary of adverse incidents whilst under this authorisation;
 - o summary of any changes to design/manufacture of devices;
 - o update on UKCA/CE marking
8. That your company has in place or puts into place mechanisms for monitoring the performance of the devices supplied under these conditions;
9. That you will cease supply of the above devices when UKCA/CE marked stocks become available;
10. That at the end of the above period or when UKCA/CE marked alternative supplies of the device become available the devices supplied by the authority of this authorisation will be returned to you or destroyed unless a further derogation is granted;
11. That your company agrees to provide details of any adverse incidents that occur in relation to the device or the use of the device via the to the reporting of adverse events for medical devices via the MORE portal found at: Medical devices: guidance for manufacturers on vigilance - GOV.UK (www.gov.uk).
12. That you submit a detailed performance surveillance plan for monthly reports to MHRA.

Please take this letter as formal approval. Please contact Devices.ExceptionalUse@mhra.gov.uk if you require any clarification in relation to this process.

Yours sincerely,



Steph Millican

Deputy Director Benefit Risk Evaluation II

Safety & Surveillance Group

MHRA

10 South Colonnade, Canary Wharf, London E14 4PU

e-mail: stephanie.millican@mhra.gov.uk



(Unofficial Translation)

หนังสือรับรองมาตรฐานการผลิตยาแผนปัจจุบันของ
สถานที่ผลิตยาในต่างประเทศ

Certificate of GMP Clearance of

Overseas Modern Pharmaceutical Manufacturers

ในราชอาณาจักร :

ชื่อสถานที่ผลิตยาในต่างประเทศ
Overseas Manufacturer Nameที่อยู่ : Biotech Park H-14/2 MIDC, Waluj, Aurangabad, 431136
Maharashtra State, Republic of India

Address

ประเทศ : Republic of India

Country

Berlin Pharmaceutical Industry Co., Ltd.

License No. IC/S Member

สำนักงานคณะกรรมการอาหารและยา โดยกองยา ได้พิจารณามาตรฐานวิธีการในการผลิตยาของสถานที่ผลิตยาในต่างประเทศดังกล่าวแล้ว เห็นว่ามีมาตรฐานการปฏิบัติที่สอดคล้องกับมาตรฐานวิธีการในการผลิตยาที่บังคับใช้ภายในประเทศไทยและยอมรับได้ จึงออกหนังสือฉบับนี้ไว้เป็นหลักฐาน โดยมีรายการผลิตภัณฑ์หรือหมวดการผลิตที่ได้รับการพิจารณาดังต่อไปนี้

รายการที่ Item No.	1		
Trade Name	GLARITUS		
Generic Name	Insulin Glargine 100 IU/mL		
Registration No.	1C 10/58 (BF)		
ประเภท Type	ยาแผนปัจจุบันสำหรับมนุษย์ (Human medicinal product), ในหมวดยาชีววัตถุ (Biological medicinal product), รูปแบบอื่นๆ (Recombinant Insulin Glargine)		
กิจกรรม Activities	Manufacturing, Primary Packaging, Secondary Packaging, Quality Control, Batch Release		
Received No	BOX-GMP-000-11483	ลงวันที่ Receiving Date:	19 กรกฎาคม 2567 19 JULY 2024

รวมทั้งสิ้น 1 รายการ
Total วันที่ Item ม 2567
Issued Date ถึง 23 JULY 2024 2569
Valid Until Date 11 AUGUST 2026

หมายเหตุ

1. หนังสือฉบับนี้ไม่สามารถใช้รับรองผลการพิจารณาเมื่อพ้นวันหมดอายุดังกล่าว เว้นแต่ จะได้นขอรับการพิจารณาใหม่ ขอต่ออายุ ขอย้ายอายุ หรือกรณีอื่น ๆ ตามข้อกำหนดด้านเอกสารที่เกี่ยวข้อง

ตรวจสอบลายมือชื่ออิเล็กทรอนิกส์

พิมพ์จากเอกสารอิเล็กทรอนิกส์

ตรวจสอบข้อมูลใบสำคัญ

สำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข



Signed by สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration of Thailand
Date: 2024-07-24T09:46:50.691+07:00

8d857bd1



2. หนังสือฉบับนี้ใช้อ้างอิงสำหรับการดำเนินกิจกรรมที่เกี่ยวข้องกับทะเบียนตำรับยาตามรายการที่ระบุ การนำหรือส่งยาแผนปัจจุบันเข้ามาในราชอาณาจักรไทย และการดำเนินการอื่น ๆ ที่เกี่ยวข้องกับสำนักงานคณะกรรมการอาหารและยา กระทรวงสาธารณสุข ไม่มีวัตถุประสงค์เพื่อใช้อ้างอิงในการดำเนินการใด ๆ ที่เกี่ยวข้องกับทะเบียนตำรับยาต่อหน่วยงานกำกับดูแลยานอกราชอาณาจักรไทย





PERÚ

Ministerio
de SaludViceministerio
de Salud PúblicaDirección General
de Medicamentos,
Insumos y Drogas

"Decenio de la Igualdad de Oportunidades para Mujeres y Hombres"
"Año de la Esperanza y el Fortalecimiento de la Democracia"

DICER-FOR-110. V: 1
21-11-2019

N° 014 -2026

CERTIFICADO

BUENAS PRÁCTICAS DE MANUFACTURA

Quien suscribe, Directora Ejecutiva de la Dirección de Inspección y Certificación de la Dirección General de Medicamentos, Insumos y Drogas, en virtud de lo dispuesto en la Ley N° 29459 - Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios, el Reglamento de Establecimientos Farmacéuticos aprobado por Decreto Supremo N° 014-2011-SA y modificatorias, la normatividad sanitaria vigente y los Informes de la Organización Mundial de la Salud;

CERTIFICA QUE:

Como resultado de la inspección realizada durante los días 09, 10, 11, 12, 13, 16 y 17 de marzo del 2026.

EL LABORATORIO	: WOCKHARDT LIMITED
CON RAZÓN SOCIAL	: WOCKHARDT LIMITED
UBICADO EN	: Planta: Biotech Park, H14/2A, MIDC Waluj, Chhatrapati Sambhaji Nagar – 431136 - Maharashtra State Planta: Biotech Park, H14/2, MIDC Waluj, Chhatrapati Sambhaji Nagar – 431136 - Maharashtra State

CUMPLE con las **BUENAS PRÁCTICAS DE MANUFACTURA** para la **FABRICACIÓN** de:

1. PRODUCTOS FARMACÉUTICOS, PRODUCTOS BIOLÓGICOS EN EL ÁREA DE:

- **Líquidos estériles de pequeño volumen:**

- Insulina Humana (ADN recombinante): Solución inyectable.
- Insulina Humana Isófana (ADN recombinante): Suspensión inyectable.
- Insulina Glargina (ADN recombinante): Solución inyectable.

Notas Aclaratorias:

1. Productos preparados asépticamente y esterilizados por Filtración.
2. La manufactura de los Productos Biológicos se lleva a cabo en áreas dedicadas y autocontenidas.
3. Durante la presente inspección se verificó la fabricación desde la obtención del IFA.

Asimismo, **CUMPLE** con las **BUENAS PRÁCTICAS DE LABORATORIO** para los **Métodos Físicos, Fisicoquímicos, Microbiológicos y Biológicos** aplicados a los productos fabricados en las áreas antes indicadas.





PERÚ

Ministerio
de Salud

Viceministerio
de Salud Pública

Dirección General
de Medicamentos,
Insumos y Drogas

"Decenio de la Igualdad de Oportunidades para Mujeres y Hombres"
"Año de la Esperanza y el Fortalecimiento de la Democracia"

DICER-FOR-110. V: 1
21-11-2019

N° 014 -2026

SE EXPIDE EL PRESENTE CERTIFICADO A SOLICITUD DE LA EMPRESA, SEGÚN LO EVALUADO EN EL INFORME TÉCNICO DE INSPECCIÓN N° 017-2026:

DROGUERÍA	: PHARMARIS PERÚ S.A.C
RAZÓN SOCIAL	: PHARMARIS PERÚ S.A.C.
REPRESENTANTE LEGAL	: Sr. RICARDO ALBERTO ALIAGA GASTELUMENDI
SEGÚN EXPEDIENTE(S)	: N° 25-127915-1 de fecha 16 de octubre del 2025, Anexo N° 1 de fecha 17 de diciembre del 2025, Anexo N° 2 de fecha 08 de enero del 2026, Anexo N° 3 de fecha 18 de febrero del 2026, Anexo N° 4 de fecha 19 de febrero del 2026, Anexo N° 5 de fecha 26 de febrero del 2026 y Anexo N° 6 de fecha 16 de marzo del 2026.

Este Certificado es válido a partir del **17 de marzo del 2026** hasta el **17 de marzo del 2031**.

Lima,

20 MAR. 2026



Q.F. GLORIA MELIDA GARCÍA MOLINA
Directora Ejecutiva
Dirección de Inspección y Certificación
DIGEMID

GMGM/CQR/KQH/ACB/acb

ЕВРАЗИЙСКИЙ ЭКОНОМИЧЕСКИЙ СОЮЗ

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ

СЕРТИФИКАТ

СООТВЕТСТВИЯ ПРОИЗВОДСТВА ЛЕКАРСТВЕННЫХ СРЕДСТВ ТРЕБОВАНИЯМ ПРАВИЛ
НАДЛЕЖАЩЕЙ ПРОИЗВОДСТВЕННОЙ ПРАКТИКИ ЕВРАЗИЙСКОГО ЭКОНОМИЧЕСКОГО СОЮЗА

№ GMP/EAEU/RU/02619-2026

Срок действия с 20.11.2025 по 19.11.2028

Выдан по итогам проведения фармацевтической инспекции в соответствии
с Правилами проведения фармацевтических инспекций, утвержденными
Решением Совета Евразийской экономической комиссии
от 3 ноября 2016 г. № 83

Министерство промышленности и торговли Российской Федерации
(Минпромторг России)

(полное и сокращенное наименования уполномоченного органа)

подтверждает следующее:

проведена фармацевтическая инспекция

Вокхард Лимитед

(полное наименование производителя)

Вокхард Лимитед, Биотек Парк, Н-14/2, МИДС, Валудж, Аурангабад-431136

Талука: Аурангабад Зона 2, Дистрикт: Аурангабад Зона 2, Индия

(адрес производственной площадки)

на основании заявления о выдаче сертификата соответствия производителя
(производителя нерезидента) лекарственных средств для медицинского
применения требованиям Правил надлежащей производственной практики
Евразийского экономического союза от 15.02.2024 № 7/24.

На основании сведений, полученных при проведении инспектирования,
последнее из которых было проведено 17.11.2025 - 20.11.2025, установлено, что
данное фармацевтическое производство соответствует требованиям Правил
надлежащей производственной практики Евразийского экономического союза,

Страница 1 из 8

000002920

GMP/EAEU/RU/02619-2026

эквивалентных Принципам и Руководству Европейского союза по надлежащей производственной практике лекарственных средств для медицинского и ветеринарного применения и принципам Системы сотрудничества фармацевтических инспекций (PIC/S).

Настоящий сертификат отражает статус производственной площадки на момент проведения фармацевтической инспекции и по истечении более 3 лет от даты последнего дня последнего инспектирования не может считаться документом, свидетельствующим о статусе соответствия. Срок действия сертификата может быть сокращен при использовании соответствующих принципов управления рисками при наличии соответствующей записи в поле «Ограничения или пояснительные заметки, касающиеся области применения настоящего сертификата».

Сертификат является действительным в случае представления всех его листов (как основных листов, так и дополнительных листов).

Аутентичность (подлинность) настоящего сертификата можно проверить в базе данных Минпромторга России.

Если сертификат не представлен в указанной базе данных, следует обратиться в уполномоченный орган, его выдавший.



Заместитель Министра

13 марта 2026 г.

(дата выдачи сертификата)

Е.Г. Приезжева

	1.2.1.11. Мягкие лекарственные формы
	1.2.1.12. Свечи (суппозитории)
	1.2.1.13. Таблетки
	1.2.1.14. Трансдермальные пластыри
	1.2.1.15. Прочая нестерильная продукция
	1.2.2. Выпускающий контроль качества (сертификация серии)
1.3	Биологическая лекарственная продукция
☒	1.3.1. Биологическая лекарственная продукция:
	1.3.1.1. Продукты крови
	1.3.1.2. Иммунобиологическая продукция
	1.3.1.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	1.3.1.4. Генотерапевтическая продукция
☒	1.3.1.5. Биотехнологическая продукция: прочая биотехнологическая продукция: раствор, суспензия
	1.3.1.6. Продукция, выделенная из животных источников или органов (тканей) человека
	1.3.1.7. Тканеинженерная продукция (продукция тканевой инженерии)
	1.3.1.8. Прочая биологическая лекарственная продукция
☒	1.3.2. Выпускающий контроль (сертификация серии) (перечень видов продукции):
	1.3.2.1. Продукты крови
	1.3.2.2. Иммунобиологическая продукция
	1.3.2.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	1.3.2.4. Генотерапевтическая продукция
☒	1.3.2.5. Биотехнологическая продукция
	1.3.2.6. Продукция, выделенная из животных источников или органов (тканей) человека



Заместитель Министра

13 марта 2026 г.

(дата выдачи сертификата)

Е.Г. Приезжева

**МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ**

GMP/EAEU/RU/02619-2026

	1.3.2.7. Тканеинженерная продукция (продукция тканевой инженерии)
	1.3.2.8. Прочая биологическая лекарственная продукция
1.4	Прочая лекарственная продукция или производственная деятельность
	1.4.1. Производство:
	1.4.1.1. Растительная продукция
	1.4.1.2. Гомеопатическая продукция
	1.4.1.3. Прочая продукция
☒	1.4.2. Стерилизация фармацевтических субстанций, вспомогательных веществ, готовой продукции:
☒	1.4.2.1. Фильтрация
	1.4.2.2. Сухожаровая стерилизация
	1.4.2.3. Стерилизация паром
	1.4.2.4. Химическая стерилизация
	1.4.2.5. Стерилизация гамма-излучением
	1.4.2.6. Стерилизация электронным излучением
	1.4.3. Прочее
1.5	Упаковка
	1.5.1. Первичная упаковка:
	1.5.1.1. Капсулы в твердой оболочке
	1.5.1.2. Капсулы в мягкой оболочке
	1.5.1.3. Жевательные лекарственные формы
	1.5.1.4. Импрегнированные лекарственные формы
	1.5.1.5. Жидкие лекарственные формы для наружного применения
	1.5.1.6. Жидкие лекарственные формы для внутреннего применения
	1.5.1.7. Медицинские газы
	1.5.1.8. Прочие твердые лекарственные формы
	1.5.1.9. Препараты, находящиеся под давлением
	1.5.1.10. Радионуклидные генераторы
	1.5.1.11. Мягкие лекарственные формы
	1.5.1.12. Свечи (суппозитории)
	1.5.1.13. Таблетки
	1.5.1.14. Трансдермальные пластыри
	1.5.1.15. Прочая нестерильная лекарственная продукция

☒	1.5.2. Вторичная упаковка
1.6	Контроль качества
☒	1.6.1. Микробиологические испытания: стерильность
	1.6.2. Микробиологические испытания: микробиологическая чистота
☒	1.6.3. Химические (физические) испытания
☒	1.6.4. Биологические испытания
2. ИМПОРТ ЛЕКАРСТВЕННОЙ ПРОДУКЦИИ	
2.1	Контроль качества импортируемой лекарственной продукции
	2.1.1. Микробиологические испытания: стерильность
	2.1.2. Микробиологические испытания: микробиологическая чистота
	2.1.3. Химические (физические) испытания
	2.1.4. Биологические испытания
2.2	Сертификация серии импортируемой лекарственной продукции
	2.2.1 Стерильная продукция:
	2.2.1.1. Производимая в асептических условиях
	2.2.1.2. Подвергаемая финишной стерилизации
	2.2.2. Нестерильная продукция
	2.2.3. Биологическая лекарственная продукция:
	2.2.3.1. Продукты крови
	2.2.3.2. Иммунобиологическая продукция
	2.2.3.3. Продукция на основе соматических клеток (продукция для терапии соматическими клетками)
	2.2.3.4. Генотерапевтическая продукция
	2.2.3.5. Биотехнологическая продукция
	2.2.3.6. Продукция, выделенная из животных источников или органов (тканей) человека
	2.2.3.7. Тканеинженерная продукция (продукция тканевой инженерии)
	2.2.3.8. Прочая биологическая лекарственная продукция
2.3	Прочая деятельность по импорту (ввозу)
	2.3.1. Площадка физического импорта (ввоза)



Заместитель Министра

13 марта 2026 г.

(дата выдачи сертификата)

Е.Г. Приезжева

МИНИСТЕРСТВО ПРОМЫШЛЕННОСТИ И ТОРГОВЛИ
РОССИЙСКОЙ ФЕДЕРАЦИИ

GMP/EAEU/RU/02619-2026

	2.3.2. Импорт промежуточной продукции, подвергающейся дальнейшей обработке
	2.3.3. Прочее
3. ПРОИЗВОДСТВЕННЫЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ СУБСТАНЦИИ	
Фармацевтическая субстанция (субстанции):	
3.1	Производство фармацевтических субстанций методом химического синтеза
	3.1.1. Производство промежуточных продуктов фармацевтической субстанции
	3.1.2. Производство неочищенной фармацевтической субстанции
	3.1.3. Солеобразование (очистка): указать (например: перекристаллизация)
	3.1.4. Прочее
3.2	Производство фармацевтических субстанций методами выделения из природных источников
	3.2.1. Выделение фармацевтических субстанций из источников растительного происхождения
	3.2.2. Выделение фармацевтических субстанций из источников животного происхождения
	3.2.3. Выделение фармацевтических субстанций из органов (тканей) человека
	3.2.4. Выделение фармацевтических субстанций из источников минерального происхождения
	3.2.5. Модификация выделенной фармацевтической субстанции
	3.2.6. Очистка выделенной фармацевтической субстанции
	3.2.7. Прочее
3.3	Производство фармацевтических субстанций с использованием биологических процессов
	3.3.1. Ферментация
	3.3.2. Производство с использованием клеточных культур
	3.3.3. Выделение (очистка)
	3.3.4. Модификация
	3.3.5. Прочее
3.4	Производство стерильных фармацевтических субстанций

	3.4.1. Фармацевтические субстанции, производимые в асептических условиях
	3.4.2. Фармацевтические субстанции, подвергаемые финишной стерилизации
3.5	Завершающие стадии производства фармацевтических субстанций
	3.5.1. Стадии физической обработки
	3.5.2. Первичная упаковка
	3.5.3. Вторичная упаковка
	3.5.4. Прочее
3.6	Контроль качества
	3.6.1. Физические (химические) испытания
	3.6.2. Микробиологические испытания (включая испытание на стерильность)
	3.6.3. Микробиологические испытания (исключая испытание на стерильность)
	3.6.4. Биологические испытания
4. ПРОЧИЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ СУБСТАНЦИИ	
Ограничения или пояснительные заметки, касающиеся области применения сертификата: —	



Заместитель Министра

13 марта 2026 г.

(дата выдачи сертификата)

Е.Г. Приезжева



MINISTERIO DE LA SALUD
AGENCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
CERTIFICADO DE BUENAS PRÁCTICAS DE FABRICACIÓN

Emitido por Renovación Automática prevista RDC 497/2021

La Agencia Nacional de Vigilancia Sanitaria ANVISA, en el ejercicio de sus asignaciones, certifica que la empresa abajo informada es periódicamente Inspeccionada y monitoreada por el Sistema Nacional de Vigilancia Sanitaria y que cumple con las directrices de Buenas Prácticas de Fabricación dadas por la legislación brasileña, la cual está en consonancia con las recomendaciones de la Organización Mundial de la Salud.

WOCKHARDT LIMITED

BIOTECH PARK, H-14/2, M.I.D.C. WALUJ, CHHATRAPATI SAMBHAJINAGAR 431136, MAHARASHTRA STATE

AURANGABAD

ÍNDIA

Líneas de Fabricación:

1) Estériles: Soluciones Parenterales de Pequeño Volumen con Preparación Aséptica; Suspensiones Parenterales de Pequeño Volumen con Preparación Aséptica

Válido hasta: 30/06/2027

Publicado en el Diario Oficial de la Unión por medio de la Resolución – RE n.º: 2.351, en la fecha de: 30/06/2025

Requerido por: GERAIS, COMÉRCIO E IMPORTAÇÃO DE MATERIAIS E EQUIPAMENTOS MEDICOS LTDA, **CNPJ**: 04.491.780/0001-70

Documento emitido electrónicamente a las: 10:03:49 en 16/07/2025 (Fecha / Zona horaria de Brasília - UTC / GMT -3 horas)

Código de control del comprobante: UOY7.XIOT.YVFD.COMB.7N0B.1VK5.6S1J.YQBI.USDY.T8DB

Comprobar la autenticidad en: http://www9.anvisa.gov.br/Peticionamento/validarcertificadoBPF_BPDA/

Health Products Regulatory Authority

CERTIFICATE NUMBER: 34213/M00281/00001

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Ireland confirms the following:

The manufacturer: **Pinewood Laboratories Limited**

Site address: **Ballymacarbry, Clonmel, E91 D434, Ireland**

OMS Organisation Id. / OMS Location Id.: **ORG-100001380 / LOC-100000597**

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. **M00281/00001** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on **2023-10-06**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572
and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in
Part 2.³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and
should not be relied upon to reflect the compliance status if more than three years have elapsed since the date
of that inspection. However, this period of validity may be reduced or extended using regulatory risk
management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or
clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).
This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the
issuing authority.

¹ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

² Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: Powders, Granules(en) 1.2.1.11 Semi-solids
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
	<i>1.5.1 Primary Packaging</i> 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: Powders, Granules(en) 1.5.1.11 Semi-solids
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>

Clarifying remarks (for public users)

The site is authorised to supply medicinal products in accordance with the provisions of Article 5 of Directive 2001/83/EC providing that it would normally conduct a manufacturing activity, as listed above, for the product concerned. Manufacture of products containing Antibiotics, Sulphonamides and Corticosteroids, but excluding Penicillins & Cephalosporins. The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.

2024-01-25

Name and signature of the authorised person of the
Competent Authority of Ireland

Confidential
Health Products Regulatory Authority
Tel: **Confidential**
Fax: **Confidential**

Dan Geoghegan
Pinewood Laboratories Limited
Unit 1-2
M50 Business Park
Ballymount
Dublin 12
D12 K6C5

Authorisation No: M00281/00002

08th November 2023

Inspection reference: 33972

Dear Mr., Geoghan,

I refer to the GMP inspection performed at Pinewood Laboratories Limited on 31st July 2023.

All correspondence relating to this inspection has been completed and implementation of corrective actions will be followed up at the next inspection.

Based on the outcome of this inspection, a GMP Certificate has been issued for manufacturing activities relating to human medicines. The scope of the certificate indicates the areas of the site that are considered to operate in accordance with the principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569.

Yours sincerely,

Peter Cannon

Digitally signed by Peter Cannon
DN: cn=Peter Cannon, o=HPRA,
ou=Compliance,
email=peter.cannon@hpra.ie, c=IE
Date: 2023.11.08 12:30:55 Z

Peter Cannon
GMP Inspector

Health Products Regulatory Authority

CERTIFICATE NUMBER: 33972/M281-002

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Ireland confirms the following:

The manufacturer: **Pinewood Healthcare Limited**

Site address: **Unit 1 2, M 50 Business Park, Ballymount, Dublin 12, D12 K6C5, Ireland**

OMS Organisation Id. / OMS Location Id.: **ORG-100010610 / LOC-100053101**

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. **M00281/00002** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted
on **2023-07-31 00:00:00.0**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572
and Commission Delegated Regulation (EU) 2017/1569³

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and
should not be relied upon to reflect the compliance status if more than three years have elapsed since the date
of that inspection. However, this period of validity may be reduced or extended using regulatory risk
management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or
clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).
This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the
issuing authority.

¹The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

²Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products	
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.3	Other importation activities
	2.3.1 Site of physical importation

Clarifying remarks (for public users)

Pinewood Laboratories Limited trades under the business name Pinewood Healthcare Limited. This site is authorised to supply medicinal products in accordance with the provisions of Article 5 of Directive 2001/83/EC providing that it would normally conduct importation, as listed above, for the product concerned. The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.

2023-11-08 00:00:00.0

Name and signature of the authorised person of the
Competent Authority of Ireland

Confidential
Health Products Regulatory Authority
Tel: *Confidential*
Fax: *Confidential*

MANUFACTURERS AUTHORISATION

1. Authorisation number **IMP00050/00001**
 2. Name of authorisation holder **Pinewood Laboratories Limited**
 3. Address(es) of manufacturing site(s)
(All authorised sites should be listed if not covered by separate licences) Ballymacarbry, Clonmel, Tipperary, E91 D434, Ireland
 4. Legally registered address
of authorisation holder (Companies Registration Office Number: 56296)
Ballymacarbry, Clonmel, Tipperary, E91 D434, E91 D434, Ireland
 5. Scope of authorisation and dosage forms ANNEX 2
 6. Legal basis of authorisation Art. 61 of Regulation (EU) No 536/2014
 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Patrick Keating
 8. Signature 
Patrick Keating (May 7, 2025 15:06 GMT+1)
-
9. Date 06 May 2025
 10. Annexes attached
 - ANNEX 1 - Scope of Authorisation
 - ANNEX 2 -Scope of Authorisation(Investigational Medicinal Products)
 - ANNEX 3 -Address(es) of Contract Manufacturing Site(s)
 - ANNEX 4 -Address(es) of Contract Laboratories
 - ANNEX 5 -Name(s) of Qualified Person(s)
 - ANNEX 6 -Names of persons responsible for quality control / production
 - ANNEX 7 -Date of Inspection on which authorisation granted
 - ANNEX 8 -Products authorised for import

Requirements to be met by a Manufacturer's Authorisation holder relating to manufacture or importation of investigational medicinal products for human use

The holder of this Manufacturer's Authorisation is reminded of the following obligations:

- To comply with the requirements to be met by an authorisation holder manufacturing or importing investigational medicinal products, as detailed in Schedule IV of the European Union (Clinical Trials) Regulations 2022 (S.I. No. 99/2022)
- To operate only within the scope and terms as detailed in this Manufacturer's Authorisation and its Annexes

To comply with Principles and Guidelines of Good Manufacturing Practice relevant to investigational medicinal products which are published by the European Commission in Volume 4 of 'The rules governing medicinal products in the European Union'

1

This annex is not applicable

Name and address of the site: Pinewood Laboratories Limited, Ballymacarbry, Clonmel,
Tipperary, E91 D434, Ireland

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
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1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for External Use 1.2.1.6 Liquids for Internal Use 1.2.1.8 Other Solid Dosage Forms - Powders & Granules 1.2.1.11 Semi-Solids <i>1.2.2 Batch Certification</i> 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.5 Liquids for External Use 1.5.1.6 Liquids for Internal Use 1.5.1.8 Other Solid Dosage Forms - Powders & Granules 1.5.1.11 Semi-Solids <i>1.5.2 Secondary Packing</i> 1.6 Quality control testing <i>1.6.2 Microbiological ; Non Sterility</i> <i>1.6.3 Chemical / Physical</i>

Any restrictions or clarifying remarks related to the scope of Manufacturing operations (for registered users)

1.2 includes the manufacture of hormonal products.

This annex is not applicable

ADDRESSES OF CONTRACT LABORATORIES ANNEX 4

This annex is not applicable

Name: Mr. James Sheehy
Qualifications: B.Sc., M.Sc., Post Graduate Diploma in Pharmaceutical Technology & Quality Systems

Name: Ms. Valeria Popova
Qualifications: Bachelors Degree in Chemistry, Masters Degree in Modern Spectral and Chromatographic Analytical Methods

Name: Mr. Daniel Geoghegan
Qualifications: Bachelors Degree in Applied Chemistry with Quality Managment, National Diploma in Applied Chemistry, M.Sc. in Pharmaceutical Analysis, Diploma in Pharmaceutical Manufacturing Technology

Name: Mr. Mark Hildebrand
Qualifications: M.Sc. in Industrial Pharmaceutical Science, Masters in Business Administration, MEngSc in Environmental Engineering Science

Name: Mr. Prasad Mandrekar
Qualifications: M.SC in Pharmaceutical Manufacturing Technology , Master of Business Administration , BSc in Pharmaceutical Science

Name: Mr Paul O'Dwyer
Qualifications: Diploma in Applied Chemistry, B.Sc in Applied Chemistry with Quality Management

NAMES OF PERSONS RESPONSIBLE FOR PRODUCTION

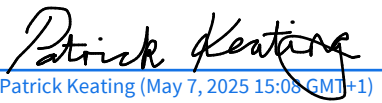
Name: Mr. Colum Honan
Qualifications: Bachelor of Engineering, Professional Certificate in Management, Professional Diploma in Management

This annex is not applicable

PRODUCTS AUTHORISED FOR IMPORT ANNEX 8

This annex is not applicable

MANUFACTURERS AUTHORISATION

1. Authorisation number **M00281/00001**
 2. Name of authorisation holder **Pinewood Laboratories Limited**
 3. Address(es) of manufacturing site(s)
(All authorised sites should be listed if not covered by separate licences) Ballymacarbry, Clonmel, Co. Tipperary, E91 D434, Ireland
 4. Legally registered address
of authorisation holder (Companies Registration Office Number: 56296)
Ballymacarbry, Clonmel, Co. Tipperary, E91 D434, Ireland
 5. Scope of authorisation and dosage forms ANNEX 1
 6. Legal basis of authorisation Art. 40 of Directive 2001/83/EC
 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Patrick Keating
 8. Signature 
[Patrick Keating \(May 7, 2025 15:08 GMT+1\)](#)
-
9. Date 06 May 2025
 10. Annexes attached
 - ANNEX 1 - Scope of Authorisation
 - ANNEX 2 -Scope of Authorisation(Investigational Medicinal Products)
 - ANNEX 3 -Address(es) of Contract Manufacturing Site(s)
 - ANNEX 4 -Address(es) of Contract Laboratories
 - ANNEX 5 -Name(s) of Qualified Person(s)
 - ANNEX 6 -Names of persons responsible for quality control / production
 - ANNEX 7 -Date of Inspection on which authorisation granted
 - ANNEX 8 -Products authorised for import

Requirements to be met by a Manufacturer's Authorisation holder relating to manufacture or importation of medicinal products for human use

The holder of this Manufacturer's Authorisation is reminded of the following obligations:

- To comply with the requirements detailed in the Schedules 2 and 3, as relevant, of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539/2007), as amended.
- To operate only within the scope and terms as detailed in this Manufacturer's Authorisation and its Annexes
- To comply with the Principles and Guidelines of Good Manufacturing Practice relevant to medicinal products for human use which are published by the European Commission in Volume 4 of 'The rules governing medicinal products in the European Union'

Name and address of the site: Pinewood Laboratories Ltd, Ballymacarbry, Clonmel, Co.
Tipperary, E91 D434, Ireland

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
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IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for External Use 1.2.1.6 Liquids for Internal Use 1.2.1.8 Other : Powders & Granules 1.2.1.11 Semi-Solids <i>1.2.2 Batch Certification</i> 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.5 Liquids for External Use 1.5.1.6 Liquids for Internal Use 1.5.1.8 Other : Powders & Granules 1.5.1.11 Semi-Solids <i>1.5.2 Secondary Packing</i> 1.6 Quality control testing <i>1.6.2 Microbiological ; Non Sterility</i> <i>1.6.3 Chemical / Physical</i>

Any restrictions or clarifying remarks related to the scope of Manufacturing operations for Public users

The site is authorised to supply medicinal products in accordance with the provisions of Article 5 of Directive 2001/83/EC providing that it would normally conduct a manufacturing activity, as listed above, for the product concerned.

Manufacture of products containing Antibiotics, Sulphonamides and Corticosteroids, but excluding Penicillins & Cephalosporins.

2	IMPORTATION OF MEDICINAL PRODUCTS
	2.1 Quality control testing for imported medicinal products 2.1.2 <i>Microbiological ; Non Sterility</i> 2.1.3 <i>Chemical / Physical</i> 2.2 Batch certification of imported medicinal products 2.2.2 <i>Non-sterile products</i> 2.3 Other importation activities 2.3.1 <i>Site of physical importation</i>

This annex is not applicable

Name and address of the site: **Athlone Laboratories Ltd, Ballymurray, Athlone, Co Roscommon, Ireland**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, Hard Shell 1.2.1.17 Other non-sterile medicinal product - Powders 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, Hard Shell <i>1.5.2 Secondary Packing</i>

Name and address of the site: **Chanelle Medical Ireland Limited, Loughrea, Co. Galway, Ireland**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.13 Tablets <i>1.5.2 Secondary Packing</i>

Name and address of the site: **Pharmapac Ltd, Unit D1, Willow Drive, Naas Enterprise Park,
Newhall, Naas, Co. Kildare, W91 E797, Ireland**

1	MANUFACTURING OPERATIONS
	1.5 Packaging <i>1.5.2 Secondary Packing</i>

Name and address of the site: **Pinewood Healthcare , Unit 1 and Unit 2, M50 Business Park,
Ballymount, Dublin 12, Ireland**

1	MANUFACTURING OPERATIONS
	1.4 Other products or processing activity <i>1.4.3 Other - Storage/Site of Physical Importation</i>

Name and address of the site: **Dexcel Limited, 1 Dexcel Street, Or Akiva, 3060000, Israel**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, Hard Shell 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, Hard Shell <i>1.5.2 Secondary Packing</i>

Name and address of the site: **Ind-Swift Limited, Off NH-21, Village Jawaharpur, Tehsil Dera Bassi, District S.A.S. Nagar (Mohali), IN-140507, India**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.13 Tablets <i>1.5.2 Secondary Packing</i>

Name and address of the site: **IPCA Laboratories Limited, Plot No. 255/1, Village Athal,
Union Territory of Dadra & Nagar Haveli, Silvassa, 396230,
India**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.13 Tablets <i>1.5.2 Secondary Packing</i>

Name and address of the site: **Milan Laboratories Private Limited, Plot Nos:
35/36/63/64/65/67/89, Jawahar Co-Op industrial Estate Ltd.,
Kamothe, Panvel (Navi Mumbai), Mumbai IN 410 209, India**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.13 Tablets <i>1.5.2 Secondary Packing</i>

Name and address of the site: **USV Private Limited, H-13, 16, 16a, 17, 18, 19, 20, 21 & E-22,
Oidc Mahatma Gandhi Udyog Nagar, Dabhel, Daman, 396210,
India**

1	MANUFACTURING OPERATIONS
	1.2 Non-sterile Products <i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets 1.5 Packaging <i>1.5.1 Primary Packing</i> 1.5.1.13 Tablets <i>1.5.2 Secondary Packing</i>

Name of Contract Laboratory:	Almac Sciences Ireland Limited
Address:	IDA Business & Technology Park, Garrycastle, Athlone, Co Westmeath, Ireland Chemical / Physical
Name of Contract Laboratory:	Microchem Laboratories Limited T/A Eurofins Lancaster Laboratories
Address:	Clogherane, Dungarvan, Co Waterford, Ireland Microbiological : Non Sterility Chemical / Physical
Name of Contract Laboratory:	Complete Laboratory Solutions
Address:	Units 3a & 8 IDA Small Business Centre, Tuam Road, Galway, H91 H520, Ireland Microbiological : Non Sterility Chemical / Physical
Name of Contract Laboratory:	Lucideon Limited
Address:	BROOMS ROAD, STONE BUSINESS PARK, STONE, ST15 0SH, United Kingdom Microbiological : Non Sterility Chemical / Physical
Name of Contract Laboratory:	Analytisches Zentrum Biopharm GmbH Berlin
Address:	Bitterfelder Str.19, 12681, Berlin, Germany Chemical / Physical
Name of Contract Laboratory:	SGS International Services Laboratory Ltd
Address:	Ringaskiddy, Cork, P43 FR63, Ireland Chemical / Physical
Name of Contract Laboratory:	CP Pharmaceuticals Limited
Address:	Ash Road North, Wrexham, LL13 9UF, United Kingdom

Chemical / Physical	
Name of Contract	Flavine Pharma France
Laboratory:	
Address:	3 Voie d'Allemagne, Vitrolles, 13127, France
	Chemical / Physical

Name:	Mr. James Sheehy
Qualifications:	B.Sc., M.Sc. Postgraduate in Pharmaceutical manufacturing Technology
Name:	Ms. Valeria Popova
Qualifications:	Bachelors Degree in Chemistry, Masters Degree in Modern Spectral and Chromatographic Analytical Methods
Name:	Mr. Daniel Geoghegan
Qualifications:	Bachelors Degree in Applied Chemistry with Quality Managment, National Diploma in Applied Chemistry, M.Sc. in Pharmaceutical Analysis, Diploma in Pharmaceutical Manufacturing Technology
Name:	Mr. Mark Hildebrand
Qualifications:	M.Sc. in Industrial Pharmaceutical Science, Masters in Business Administration, MEngSc in Environmental Engineering Science
Name:	Mr. Prasad Mandrekar
Qualifications:	M.SC in Pharmaceutical Manufacturing Technology , Master of Business Administration , BSc in Pharmaceutical Science

Name: Mr Paul O'Dwyer
Qualifications: Diploma in Applied Chemistry, B.Sc in Applied Chemistry with Quality Management

NAMES OF PERSONS RESPONSIBLE FOR PRODUCTION

Name: Mr. Colum Honan
Qualifications: Bachelor of Engineering, Professional Certificate in Management, Professional Diploma in Management

This annex is not applicable

PRODUCT AUTHORISED FOR IMPORT**ANNEX 8**

Products authorised to be manufactured/imported (in accordance with Article 41 and 42 of Directive 2001/83/EC and/or Article 45 and 46 of Directive 2001/82/EC, as amended).

Name of Contract Manufacturer: **Dexcel Limited**
Address: **1 Dexcel Street, Or Akiva, 3060000**
Country: **Israel**

Product Type:		Non-sterile products	Dosage Form: Capsules, Hard Shell	
Details of Imported Product				
Description	Strength	Active Ingredient	Activities by MIA holder	
Hard shell capsules	100mg	Minocycline	Batch Certification	Physical Importation

Name of Contract Manufacturer:

Ind-Swift Limited

Address:

**Off NH-21, Village Jawaharpur, Tehsil Dera Bassi,
District S.A.S. Nagar (Mohali), IN-140507**

Country:

India

Product Type:		Non-sterile products	Dosage Form: Tablets	
Details of Imported Product				
Description	Strength	Active Ingredient	Activities by MIA holder	
Tablets	10mg	Atorvastatin	Batch Certification	Physical Importation
Tablets	20mg	Atorvastatin	Batch Certification	Physical Importation
Tablets	40mg	Atorvastatin	Batch Certification	Physical Importation
Tablets	80mg	Atorvastatin	Batch Certification	Physical Importation

Name of Contract Manufacturer:

IPCA Laboratories Limited

Address:

**Plot No. 255/1, Village Athal, Union Territory of
Dadra & Nagar Haveli, Silvassa, 396230**

Country:

India

Product Type:		Non-sterile products	Dosage Form: Tablets	
Details of Imported Product				
Description	Strength	Active Ingredient	Activities by MIA holder	
Tablets	10mg	Cetirizine hydrochloride	Batch Certification	Physical Importation
Tablets	7.5mg	Zopiclone	Batch Certification	Physical Importation

Name of Contract Manufacturer: **Milan Laboratories Private Limited, Plot Nos: 35/36/63/64/65/67/89**

Address: **Jawahar Co-Op industrial Estate Ltd., Kamothe, Panvel (Navi Mumbai), Mumbai IN 410 209**

Country: **India**

Product Type:		Non-sterile products	Dosage Form: Tablets	
Details of Imported Product				
Description	Strength	Active Ingredient	Activities by MIA holder	
Paratabs	500mg	Paracetamol	Batch Certification	N/A

Name of Contract Manufacturer:

USV Private Limited

Address:

**H-13, 16, 16a, 17, 18, 19, 20, 21 & E-22, Oidc
Mahatma Gandhi Udyog Nagar, Dabhel, Daman,
396210**

Country:

India

Product Type:		Non-sterile products	Dosage Form: Tablets	
Details of Imported Product				
Description	Strength	Active Ingredient	Activities by MIA holder	
Tablets	500mg	Metformin	Batch Certification	Physical Importation
Tablets	850mg	Metformin	Batch Certification	Physical Importation
Tablets	1000mg	Metformin	Batch Certification	Physical Importation



UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION (MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation number **W00190/00002**
2. Name of authorisation holder **Pinewood Laboratories Limited**
3. Legally registered address of authorisation holder **(Companies Registration Office Number: 56296)
Ballymacarbry, Clonmel, Co. Tipperary, E91 D434, Ireland**
4. Address of site **Unit 1-2, Ballymount, M50 Business Park, Dublin 12, D12 K6C5, Ireland**
5. Scope of authorisation **See Annex 1**
6. Legal basis of authorisation **Art. 77(1) of Directive 2001/83/EC.**
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation
Niamh O'Donnell
8. Signature *Niamh O'Donnell*
9. Date of authorisation **22 April 2025**
10. Annexes attached

Annex 1	Scope of wholesale distribution authorisation
Annex 3	Name(s) of responsible person(s)

ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: **Pinewood Laboratories Limited, Unit 1-2, Ballymount, M50 Business Park, Dublin 12, D12 K6C5, Ireland**

1. MEDICINAL PRODUCTS

- 1.1 With a Marketing Authorisation in EEA country(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market*
- 1.3 Without a Marketing Authorisation in the EEA and intended for exportation

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.2 Holding

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1. Products according to Art. 83 of 2001/83/EC [1]
 - 3.1.1 Narcotic or psychotropic products
- 3.3 Other products: (please specify here or see remarks)
 - 3.3.1 Prescription only medicinal products
 - 3.3.2 Medicinal products for general sale
 - 3.3.3 Over the counter medicinal products for sale through pharmacies only
 - 3.3.4 Unauthorised medicinal products
 - 3.3.11 Exempt medicinal products
 - 3.3.12 Biological products

[1] Without prejudice to further authorisations as may be required according to national legislation

Annex 3

Name of Responsible Person: Mr. Conor O'Brien

Name(s) of Deputy Responsible Person(s): Ms. Lauren McCarthy

Schedule 1

Requirements to be met by an authorisation holder as per Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007)*

1. In this Schedule, the term ‘marketing authorisation’ includes a certificate of registration and a certificate of traditional-use registration.
2. (1) Subject to subparagraph (2), and paragraph 2A, the authorisation holder shall obtain his or her supplies of medicinal products only from persons —
 - (a) who are themselves the holders of a manufacturer’s authorisation or a wholesaler’s authorisation in respect of such products, or
 - (b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture or the wholesale distribution of such products.
- 2A. The authorisation holder shall only order and obtain his or her supplies of medicinal products which are intended for onward supply through his or her wholesaler’s authorisation via an account or equivalent supply arrangement established with his or her supplier exclusively for the purpose of obtaining medicinal products for wholesale distribution.
- (2) Where a medicinal product is directly received from a state other than an EEA State but not imported into the State —
 - (a) subparagraph (1) shall not apply, and
 - (b) the authorisation holder shall ensure that the medicinal product is obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the state concerned,
- 3.(1) Subject to subparagraph (2) and paragraph 17, the authorisation holder shall not sell by wholesale any medicinal product —
 - (a) other than a product to which the authorisation relates,
 - (b) unless there has been granted in respect of such product, a marketing authorisation which is for the time being in force, and
 - (c) unless the sale of such product is in conformity with the provisions of its marketing authorisation.
- (2) Subparagraph (1)(b) and (c) shall not apply —
 - (a) until 30 April 2011, to the sale by wholesale of any traditional herbal medicinal product that was already on the market in the State, on the date of the coming into force of these Regulations;
 - (b) to the sale by wholesale of an exempt medicinal product; and
 - (c) to the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation by virtue of legislation adopted by that State under Article 5.2 of the 2001 Directive.
4. The authorisation holder shall only sell medicinal products by wholesale to persons —
 - (a) who are themselves the holders of a wholesaler’s authorisation relating to those products,
 - (b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the wholesale distribution of those products,
 - (c) who are the holders of a manufacturer’s authorisation for use in the manufacture of medicinal products to which the said manufacturer’s authorisation relates,
 - (d) who are authorised or entitled to supply the said medicinal products to the public,
 - (e) who are lawfully entitled to administer those products to patients in the course of a professional practice or business as a hospital, or
 - (f) who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in a state other than an EEA State in accordance with the applicable legal and administrative provisions of the state concerned.
- 4A. In the case of paragraph 4(d), the authorisation holder shall only supply medicinal products via an account or equivalent supply arrangement established with the recipient exclusively for the purpose of supply to the public and no further wholesale distribution of the products shall take place.
5. The authorisation holder shall provide and maintain such staff, premises, installations, equipment and procedures for the handling, storage and distribution of the medicinal products that he or she handles, stores or distributes under his or her authorisation, as are necessary to avoid deterioration of the products and he or she shall not use for such purposes premises other than those specified in his or her authorisation.
- 5A. The authorisation holder shall maintain a quality system setting out responsibilities, processes and risk management measures in relation to his or her activities.
6. (1) The authorisation holder shall at all times have at his or her disposal the services of a responsible person who possesses in the opinion of the HPRA:
 - (a) knowledge of the activities to be carried out and of the procedures to be performed under the authorisation which is adequate for performing the functions of the responsible person; and
 - (b) experience in those activities and procedures which is adequate for those purposes.
- (2) The functions of the responsible person shall be to ensure that in relation to medicinal products —
 - (a) the conditions under which the wholesaler’s authorisation has been granted have been, and are being, complied with, and
 - (b) the quality of the products that are being handled by the authorisation holder is maintained in accordance with the requirements of the marketing authorisation that are applicable to those products.
- (3) The authorisation holder shall —
 - (a) notify the Authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of responsible person;
 - (b) notify the Authority of any change to the responsible person; and
 - (c) shall not permit any person to act as responsible person other than the person named in his or her authorisation as the responsible person, or subject to subparagraphs (4) and (5) any other such person whose name is notified to the Authority.
- (4) Where, after giving the authorisation holder and the person acting as the responsible person the opportunity of making representations (either orally or in writing), the Authority is of the opinion that —
 - (a) the person so acting does not satisfy the provisions of subparagraph (1) as respects qualifications and experience, or
 - (b) he or she is failing to carry out the functions referred to in subparagraph (2) adequately or at all, and has notified the authorisation

holder accordingly in writing, the holder shall not permit that person to continue to act as the responsible person so long as the said notification has not been withdrawn by the Authority.

(5) The Authority may require the authorisation holder to temporarily suspend the person acting as such responsible person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his or her functions as referred to in subparagraph (2) and the authorisation holder shall not permit that person to act as the responsible person pending the determination of such proceedings. However, nothing in this paragraph shall affect the right of the responsible person pursuant to his or her contract of employment to receive full pay during the period of any such suspension.

7. The authorisation holder shall notify the Authority of any proposed structural alteration to, or discontinuation of use of, premises to which the authorisation relates or premises that have been approved from time to time by the Authority.

8. (1) The authorisation holder shall keep available for inspection by officers of the Authority, for a period of not less than five years, records giving for each transaction in respect of medicinal products received, dispatched or brokered at least the following information:

- the date of receipt, supply or brokering,
- the name of the medicinal product,
- the quantity received, supplied or brokered, and
- the name and address of the supplier, consignee or broker, as appropriate in the case of products required to bear safety features, the batch number of the medicinal product received, supplied or brokered.

(2) The records referred to in subparagraph (1) may be provided via image medium or other data medium, provided that the data, when made readable, match the original documentation in appearance and content, are available at all times, can be made readable without delay and can be analysed by automated means.

9. The authorisation holder shall have an emergency plan which will ensure the effective implementation of any recall from the market of any such product, or batch thereof, that may be ordered by the Authority or carried out in cooperation with the manufacturer or holder of the marketing authorisation for the medicinal product concerned.

10. The authorisation holder, in making a sale by wholesale to persons referred to in paragraph 4(d), (e) and (f)), shall enclose with the medicinal product a document that makes it possible for such persons to ascertain:

- the date on which the sale took place,
- the name and pharmaceutical form of the product supplied,
- the quantity of the product supplied, and
- the name and address of the supplier and consignor in the case of products required to bear safety features, the batch number of the medicinal product.

11. The authorisation holder shall, in respect of a medicinal product that has actually been placed on the market in the State and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product to the persons referred to in paragraph 4(d) and (e), so that the needs of patients in the State in respect of such medicinal product are covered.

12. Where an authorisation holder proposes to import from another EEA State a medicinal product in respect of which he is not the holder of the relevant marketing authorisation or is not acting on behalf of such person, he or she shall notify the holder of the authorisation and —

(a) in the case of a marketing authorisation other than a Community marketing authorisation, notify the Authority and pay the appropriate fee to the Authority in respect of the notification, or

(b) in the case of a Community marketing authorisation, notify the Agency and pay the appropriate fee to the Agency, in accordance with Article 76(3) of the 2001 Directive.

13. The authorisation holder shall comply with the principles and guidelines of good distribution practice for medicinal products published by the Commission pursuant to Article 84 of the 2001 Directive.

14. The authorisation holder shall, on being informed by the Authority or by the holder of the marketing authorisation, that any batch of any medicinal product to which the wholesaler's authorisation relates, has been found not to conform as regards the provisions of the relevant marketing authorisation, or as regards the strength, quality or purity with the appropriate specification for that product, if so directed, immediately withhold such batch from sale or exportation, and if so directed by the Authority, insofar as may be reasonably practicable, immediately withdraw from sale any supplies of that batch held by him or her and immediately recall all supplies already sold or distributed from that batch.

15. The authorisation holder shall, on being informed by the Authority that a medicinal product to which the wholesaler's authorisation relates, has been found to give rise to concerns in regard to its safety or efficacy, if so directed by the Authority, immediately withhold such product from sale, supply or exportation and insofar as may be reasonably practicable, immediately recall all supplies already sold or distributed by him or her.

16. The authorisation holder shall permit at all reasonable times such inspections, by officers of the Authority, as may be required to satisfy the Authority that the conditions of the authorisation are being complied with.

17. (1) Where and insofar as the wholesaler's authorisation relates to an exempt sourced medicinal products, the authorisation holder shall only source such products —

17. (1) Where and insofar as the wholesaler's authorisation relates to an exempt medicinal product, the authorisation holder shall only source such product—

(a) in response to an order, or in anticipation of an order, which satisfies the requirements of paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007)*; and

(b) where the conditions set out in subparagraphs (2) to (9) are complied with.

(2) The authorisation holder shall, in the case of each consignment of an exempt medicinal product received by him or her, make, and keep available for inspection by officers of the Authority, for a period of not less than five years, written records showing the following particulars —

(a) the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the particular medicinal product is to be sold or supplied in the State;

(b) the dosage form;

(c) the trading style or name of the manufacturer of the medicinal product;

(d) in respect of each active constituent of the medicinal product, any international non-proprietary name or the monograph name or, where that constituent does not have an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of that constituent;

- (e) the quantity of medicinal product which has been received;
 - (f) the batch number of the medicinal product which has been received; and
 - (g) the name and address of the manufacturer of that medicinal product in the form in which it was received and, if the person who supplied the medicinal product is not the manufacturer, the name and address of such supplier.
- (3) Where the authorisation holder sells or supplies an exempt medicinal product, he or she shall, in addition to those records mentioned in paragraph 8(1) and subparagraph (2), make and maintain written records relating to —
- (a) the batch number of the batch of the product from which each sale or supply was made;
 - (b) details of any suspected adverse reaction to the product so sold or supplied of which he or she becomes aware; and
 - (c) details of any quality defect relating to the product so sold or supplied of which he or she becomes aware.
- (4) The authorisation holder shall not issue any advertisement, other than one that states only the trade name, pack size, price and dose, relating to an exempt medicinal product or make any representations in respect of such product.
- (5) The authorisation holder shall inform the Authority forthwith of any matter, including suspected adverse reactions and quality defects, coming to his or her attention, in respect of an exempt medicinal product that has been sourced by him or her.
- (6) The authorisation holder shall cease supplying an exempt medicinal product if he or she has received a notice in writing from the Authority directing that, as from a date specified in that notice, a particular product or class of products shall no longer be sourced or supplied.
- (7) The authorisation holder shall, on being informed by the Authority, or by the manufacturer or person who supplied the medicinal product to the holder of the authorisation, that the medicinal product cannot be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality or efficacy for such administration, immediately withdraw any supplies of that product held by him or her and immediately recall all supplies already sold or distributed.
- (8) With effect from the 1 January 2008, the authorisation holder shall, not later than seven days of his or her receipt of a consignment of an exempt medicinal product, notify the Authority of each such receipt. Each such notification shall include the particulars set out in subparagraph (2).
- (9) With effect from the 1 January 2009, the notifications referred to in subparagraph (8) shall, except in exceptional circumstances, be communicated electronically to the Authority and within a timeframe of two working days from the date of the receipt of each such consignment.
- (10) In this paragraph — ‘common name’ means the international non-proprietary name, or, if one does not exist, the usual common name; ‘international non-proprietary name’ means the international non-proprietary name recommended by the World Health Organisation; and ‘monograph name’ means the name or approved synonym which appears at the head of a monograph in the current edition of the European Pharmacopoeia, the British Pharmacopoeia, or a foreign or international compendium of standards and ‘current’ in this definition means current at the time the notice is sent to the Authority.
18. In paragraphs 3(1)(b) and (c), 4, 6(2)(b) and 13, every reference to a medicinal product shall be a reference to a medicinal product that is intended to be placed on the market in the State or in another EEA State.
19. (1) Subject to subparagraph (2), the authorisation holder shall verify that the medicinal products received are not falsified by checking any safety features on the outer packaging, in accordance with Regulation (EU) 2016/161.
- (2) Subparagraph (1) shall not apply where a medicinal product is directly received from a third country but not imported into the State.
20. The authorisation holder shall immediately inform the Authority and, where applicable, the holder of the relevant marketing authorisation, certificate of registration certificate of traditional-use registration, or in the case of a product intended for a state other than an EEA State the holder of the relevant authorisation in that state if he or she receives, is offered or sells by wholesale a medicinal product and he or she knows, or subsequently becomes aware after having sold by wholesale the product, or there are sufficient grounds to suspect, that the product is a falsified medicinal product.
21. Where a medicinal product is obtained from another wholesale distributor, the authorisation holder shall verify that the supplying wholesale distributor —
- (a) complies with the principles and guidelines of good distribution practice published by the Commission pursuant to Article 84 of the 2001 Directive, and
 - (b) holds a wholesaler’s authorisation, or an equivalent authorisation granted in another EEA State.
22. Where a medicinal product is obtained from a manufacturer or importer, the authorisation holder shall verify that the supplying manufacturer or importer holds an appropriate marketing authorisation, certificate of registration, certificate of traditional-use registration or in the case of a product obtained from a state other than an EEA State, the relevant authorisation issued in that state.
23. Where a medicinal product is obtained through brokering, the authorisation holder shall verify that the broker involved fulfils the requirements set out in these Regulations and the 2001 Directive.
24. (1) Notwithstanding anything to the contrary in these Regulations
- (a) until 31 December 2024, the Board shall allow the import of medicinal products from parts of the United Kingdom other than Northern Ireland by holders of a wholesaler’s authorisation that are not in possession of a relevant manufacturing authorisation following submission of a request by the holders of the marketing authorisation for the medicinal products provided that all of the following conditions are fulfilled—
 - (i) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 51(3) of the 2001 Directive, or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20, first paragraph, point (b) of the 2001 Directive,
 - (ii) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 51(1) of the 2001 Directive, or in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51(1) of the 2001 Directive,
 - (iii) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union Law, by the Board or by the Commission,
 - (iv) the medicinal products are only made available to patients or end-consumers in the State, and
 - (v) the medicinal products bear the safety features referred to in Article 54, point (o) of the 2001 Directive.
- (2) Notwithstanding anything to the contrary in these Regulations, until 31 December 2024, Article 80, first subparagraph, point (b) of the 2001 Directive shall not apply to imports that fulfil the conditions laid down in paragraph (1).

This authorisation is subject to any other requirement specified as per the Medicinal Products (Control of Wholesale Distribution)

MANUFACTURERS AUTHORISATION

- | | |
|--|--|
| 1. Authorisation number | M00281/00002 |
| 2. Name of authorisation holder | Pinewood Laboratories Limited |
| 3. Address(es) of manufacturing site(s)
(All authorised sites should be listed if not covered by separate licences) | Unit 1-2, M50 Business Park, Ballymount, Dublin 12, D12 K6C5, Ireland |
| 4. Legally registered address of authorisation holder | (Companies Registration Office Number: 56296)
Ballymacarbry, Clonmel, Co. Tipperary, E91 D434, Ireland |
| 5. Scope of authorisation and dosage forms | ANNEX 1 |
| 6. Legal basis of authorisation | Art. 40 of Directive 2001/83/EC |
| 7. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Paulina Nulty |
| 8. Signature | <u><i>Paulina Nulty</i></u> |
| 9. Date | 04 October 2023 |
| 10. Annexes attached | ANNEX 1 - Scope of Authorisation
ANNEX 2 -Scope of Authorisation(Investigational Medicinal Products)
ANNEX 3 -Address(es) of Contract Manufacturing Site(s)
ANNEX 4 -Address(es) of Contract Laboratories
ANNEX 5 -Name(s) of Qualified Person(s)
ANNEX 6 -Names of persons responsible for quality control / production
ANNEX 7 -Date of Inspection on which authorisation granted
ANNEX 8 -Products authorised for import |

Requirements to be met by a Manufacturer's Authorisation holder relating to manufacture or importation of medicinal products for human use

The holder of this Manufacturer's Authorisation is reminded of the following obligations:

- To comply with the requirements detailed in the Schedules 2 and 3, as relevant, of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539/2007), as amended.
- To operate only within the scope and terms as detailed in this Manufacturer's Authorisation and its Annexes
- To comply with the Principles and Guidelines of Good Manufacturing Practice relevant to medicinal products for human use which are published by the European Commission in Volume 4 of 'The rules governing medicinal products in the European Union'

Name and address of the site: Pinewood Healthcare, Unit 1-2, M50 Business Park,
Ballymount, Dublin 12, D12 K6C5, Ireland

Human Medicinal Products

Authorised Operations

IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

2	IMPORTATION OF MEDICINAL PRODUCTS
	2.3 Other importation activities <i>2.3.1 Site of physical importation</i>

Any restrictions or clarifying remarks related to the scope of these Importation operations for Public users

This site is authorised to supply medicinal products in accordance with the provisions of Article 5 of Directive 2001/83/EC providing that it would normally conduct an importation activity, as listed above, for the product concerned.

This annex is not applicable

This annex is not applicable

ADDRESSES OF CONTRACT LABORATORIES

ANNEX 4

This annex is not applicable

NAMES OF QUALIFIED PERSONS

ANNEX 5

Name: Mr. James Sheehy

Qualifications: B.Sc., M.Sc.,

Name: Ms. Valeria Popova

Qualifications: Bachelors Degree in Chemistry, Masters Degree in Modern Spectral and Chromatographic Analytical Methods

Name: Mr. Daniel Geoghegan

Qualifications: Bachelors Degree in Applied Chemistry with Quality Managment, National Diploma in Applied Chemistry, M.Sc. in Pharmaceutical Analysis, Diploma in Pharmaceutical Manufacturing Technology

Name: Mr. Mark Hildebrand

Qualifications: M.Sc. in Industrial Pharmaceutical Science, Masters in Business Administration, MEngSc in Environmental Engineering Science

NAMES OF PERSONS RESPONSIBLE FOR QUALITY CONTROL

ANNEX 6

Name: Mr Paul O'Dwyer

Qualifications: Diploma in Applied Chemistry, B.Sc in Applied Chemistry with
Quality Management

NAMES OF PERSONS RESPONSIBLE FOR PRODUCTION

Name: Mr. Conor O'Brien

This annex is not applicable

PRODUCTS AUTHORISED FOR IMPORT ANNEX 8

This annex is not applicable



**UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION
(MEDICINAL PRODUCTS FOR HUMAN USE)**

- | | | | | | | | |
|--|--|---------|---|---------|---|---------|----------------------------------|
| 1. Authorisation number | W00190/00003 | | | | | | |
| 2. Name of authorisation holder | Pinewood Laboratories Limited | | | | | | |
| 3. Legally registered address of authorisation holder | (Companies Registration Office Number: 56296)
Ballymacarbry, Clonmel, Tipperary, Ireland | | | | | | |
| 4. Address of site | Ballymacarbry, Clonmel, Tipperary, Ireland | | | | | | |
| 5. Scope of authorisation | See Annex 1 | | | | | | |
| 6. Legal basis of authorisation | Art. 77(1) of Directive 2001/83/EC. | | | | | | |
| 7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation | Niamh O'Donnell | | | | | | |
| 8. Signature | <u><i>Niamh O'Donnell</i></u> | | | | | | |
| 9. Date of authorisation | 14 May 2025 | | | | | | |
| 10. Annexes attached | <table border="0"><tr><td>Annex 1</td><td>Scope of wholesale distribution authorisation</td></tr><tr><td>Annex 2</td><td>Address(es) of contract wholesale distribution sites and their authorisation number</td></tr><tr><td>Annex 3</td><td>Name(s) of responsible person(s)</td></tr></table> | Annex 1 | Scope of wholesale distribution authorisation | Annex 2 | Address(es) of contract wholesale distribution sites and their authorisation number | Annex 3 | Name(s) of responsible person(s) |
| Annex 1 | Scope of wholesale distribution authorisation | | | | | | |
| Annex 2 | Address(es) of contract wholesale distribution sites and their authorisation number | | | | | | |
| Annex 3 | Name(s) of responsible person(s) | | | | | | |

ANNEX 1
SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: **Pinewood Laboratories Limited , Ballymacarbry, Clonmel, Tipperary, Ireland**

1. MEDICINAL PRODUCTS

- 1.1 With a Marketing Authorisation in EEA country(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market*
- 1.3 Without a Marketing Authorisation in the EEA and intended for exportation

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.3 Supply
- 2.4 Export

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1. Products according to Art. 83 of 2001/83/EC [1]
 - 3.1.1 Narcotic or psychotropic products
- 3.2 Products requiring low temperature handling
- 3.3 Other products: (please specify here or see remarks)
 - 3.3.1 Prescription only medicinal products
 - 3.3.2 Medicinal products for general sale
 - 3.3.3 Over the counter medicinal products for sale through pharmacies only
 - 3.3.4 Unauthorised medicinal products
 - 3.3.11 Exempt medicinal products
 - 3.3.12 Biological products

Any restrictions or clarifying remarks related to the scope of these wholesaling operations:

Not all contract storage sites listed in Annex 2 are authorised to hold all categories of medicinal products listed in Section 3

[1] Without prejudice to further authorisations as may be required according to national legislation

Annex 2

Address(es) of contract wholesale distribution sites and their authorisation number	Pinewood Laboratories Limited Unit 1 & Unit 2 M50 Business Park Ballymount Dublin 12 Ireland	W00190/00002
	United Drug Distributors Ireland Limited United Drug House, Magna Drive Magna Business Park Citywest Road Dublin 24, D24 XKE5 Ireland	W11902/00001
	Interlink Ireland Ltd T/A DPD Ireland Athlone Business Park Dublin Road Athlone	W11019/00001

Westmeath
Ireland

Annex 3

Name of Responsible Person: Ms. Valeria Popova

Name(s) of Deputy Responsible
Person(s): Mr. Conor O'Brien

Schedule 1

Requirements to be met by an authorisation holder as per Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538 of 2007)*

1. In this Schedule, the term ‘marketing authorisation’ includes a certificate of registration and a certificate of traditional-use registration.
2. (1) Subject to subparagraph (2), and paragraph 2A, the authorisation holder shall obtain his or her supplies of medicinal products only from persons —
 - (a) who are themselves the holders of a manufacturer’s authorisation or a wholesaler’s authorisation in respect of such products, or
 - (b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the manufacture or the wholesale distribution of such products.
- 2A. The authorisation holder shall only order and obtain his or her supplies of medicinal products which are intended for onward supply through his or her wholesaler’s authorisation via an account or equivalent supply arrangement established with his or her supplier exclusively for the purpose of obtaining medicinal products for wholesale distribution.
- (2) Where a medicinal product is directly received from a state other than an EEA State but not imported into the State —
 - (a) subparagraph (1) shall not apply, and
 - (b) the authorisation holder shall ensure that the medicinal product is obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the state concerned,
- 3.(1) Subject to subparagraph (2) and paragraph 17, the authorisation holder shall not sell by wholesale any medicinal product —
 - (a) other than a product to which the authorisation relates,
 - (b) unless there has been granted in respect of such product, a marketing authorisation which is for the time being in force, and
 - (c) unless the sale of such product is in conformity with the provisions of its marketing authorisation.
- (2) Subparagraph (1)(b) and (c) shall not apply —
 - (a) until 30 April 2011, to the sale by wholesale of any traditional herbal medicinal product that was already on the market in the State, on the date of the coming into force of these Regulations;
 - (b) to the sale by wholesale of an exempt medicinal product; and
 - (c) to the export to an EEA State, or supply for the purposes of such export, of a medicinal product which may be placed on the market in that State without a marketing authorisation by virtue of legislation adopted by that State under Article 5.2 of the 2001 Directive.
4. The authorisation holder shall only sell medicinal products by wholesale to persons —
 - (a) who are themselves the holders of a wholesaler’s authorisation relating to those products,
 - (b) who are the holders of an authorisation granted by the competent authority of another EEA State authorising the wholesale distribution of those products,
 - (c) who are the holders of a manufacturer’s authorisation for use in the manufacture of medicinal products to which the said manufacturer’s authorisation relates,
 - (d) who are authorised or entitled to supply the said medicinal products to the public,
 - (e) who are lawfully entitled to administer those products to patients in the course of a professional practice or business as a hospital, or
 - (f) who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in a state other than an EEA State in accordance with the applicable legal and administrative provisions of the state concerned.
- 4A. In the case of paragraph 4(d), the authorisation holder shall only supply medicinal products via an account or equivalent supply arrangement established with the recipient exclusively for the purpose of supply to the public and no further wholesale distribution of the products shall take place.
5. The authorisation holder shall provide and maintain such staff, premises, installations, equipment and procedures for the handling, storage and distribution of the medicinal products that he or she handles, stores or distributes under his or her authorisation, as are necessary to avoid deterioration of the products and he or she shall not use for such purposes premises other than those specified in his or her authorisation.
- 5A. The authorisation holder shall maintain a quality system setting out responsibilities, processes and risk management measures in relation to his or her activities.
6. (1) The authorisation holder shall at all times have at his or her disposal the services of a responsible person who possesses in the opinion of the HPRA:
 - (a) knowledge of the activities to be carried out and of the procedures to be performed under the authorisation which is adequate for performing the functions of the responsible person; and
 - (b) experience in those activities and procedures which is adequate for those purposes.
- (2) The functions of the responsible person shall be to ensure that in relation to medicinal products —
 - (a) the conditions under which the wholesaler’s authorisation has been granted have been, and are being, complied with, and
 - (b) the quality of the products that are being handled by the authorisation holder is maintained in accordance with the requirements of the marketing authorisation that are applicable to those products.
- (3) The authorisation holder shall —
 - (a) notify the Authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of responsible person;
 - (b) notify the Authority of any change to the responsible person; and
 - (c) shall not permit any person to act as responsible person other than the person named in his or her authorisation as the responsible person, or subject to subparagraphs (4) and (5) any other such person whose name is notified to the Authority.
- (4) Where, after giving the authorisation holder and the person acting as the responsible person the opportunity of making representations (either orally or in writing), the Authority is of the opinion that —
 - (a) the person so acting does not satisfy the provisions of subparagraph (1) as respects qualifications and experience, or
 - (b) he or she is failing to carry out the functions referred to in subparagraph (2) adequately or at all, and has notified the authorisation

holder accordingly in writing, the holder shall not permit that person to continue to act as the responsible person so long as the said notification has not been withdrawn by the Authority.

(5) The Authority may require the authorisation holder to temporarily suspend the person acting as such responsible person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his or her functions as referred to in subparagraph (2) and the authorisation holder shall not permit that person to act as the responsible person pending the determination of such proceedings. However, nothing in this paragraph shall affect the right of the responsible person pursuant to his or her contract of employment to receive full pay during the period of any such suspension.

7. The authorisation holder shall notify the Authority of any proposed structural alteration to, or discontinuation of use of, premises to which the authorisation relates or premises that have been approved from time to time by the Authority.

8. (1) The authorisation holder shall keep available for inspection by officers of the Authority, for a period of not less than five years, records giving for each transaction in respect of medicinal products received, dispatched or brokered at least the following information:

- the date of receipt, supply or brokering,
- the name of the medicinal product,
- the quantity received, supplied or brokered, and
- the name and address of the supplier, consignee or broker, as appropriate in the case of products required to bear safety features, the batch number of the medicinal product received, supplied or brokered.

(2) The records referred to in subparagraph (1) may be provided via image medium or other data medium, provided that the data, when made readable, match the original documentation in appearance and content, are available at all times, can be made readable without delay and can be analysed by automated means.

9. The authorisation holder shall have an emergency plan which will ensure the effective implementation of any recall from the market of any such product, or batch thereof, that may be ordered by the Authority or carried out in cooperation with the manufacturer or holder of the marketing authorisation for the medicinal product concerned.

10. The authorisation holder, in making a sale by wholesale to persons referred to in paragraph 4(d), (e) and (f), shall enclose with the medicinal product a document that makes it possible for such persons to ascertain:

- the date on which the sale took place,
- the name and pharmaceutical form of the product supplied,
- the quantity of the product supplied, and
- the name and address of the supplier and consignor in the case of products required to bear safety features, the batch number of the medicinal product.

11. The authorisation holder shall, in respect of a medicinal product that has actually been placed on the market in the State and within the limits of his or her responsibility, ensure appropriate and continued supplies of that product to the persons referred to in paragraph 4(d) and (e), so that the needs of patients in the State in respect of such medicinal product are covered.

12. Where an authorisation holder proposes to import from another EEA State a medicinal product in respect of which he is not the holder of the relevant marketing authorisation or is not acting on behalf of such person, he or she shall notify the holder of the authorisation and —

(a) in the case of a marketing authorisation other than a Community marketing authorisation, notify the Authority and pay the appropriate fee to the Authority in respect of the notification, or

(b) in the case of a Community marketing authorisation, notify the Agency and pay the appropriate fee to the Agency, in accordance with Article 76(3) of the 2001 Directive.

13. The authorisation holder shall comply with the principles and guidelines of good distribution practice for medicinal products published by the Commission pursuant to Article 84 of the 2001 Directive.

14. The authorisation holder shall, on being informed by the Authority or by the holder of the marketing authorisation, that any batch of any medicinal product to which the wholesaler's authorisation relates, has been found not to conform as regards the provisions of the relevant marketing authorisation, or as regards the strength, quality or purity with the appropriate specification for that product, if so directed, immediately withhold such batch from sale or exportation, and if so directed by the Authority, insofar as may be reasonably practicable, immediately withdraw from sale any supplies of that batch held by him or her and immediately recall all supplies already sold or distributed from that batch.

15. The authorisation holder shall, on being informed by the Authority that a medicinal product to which the wholesaler's authorisation relates, has been found to give rise to concerns in regard to its safety or efficacy, if so directed by the Authority, immediately withhold such product from sale, supply or exportation and insofar as may be reasonably practicable, immediately recall all supplies already sold or distributed by him or her.

16. The authorisation holder shall permit at all reasonable times such inspections, by officers of the Authority, as may be required to satisfy the Authority that the conditions of the authorisation are being complied with.

17. (1) Where and insofar as the wholesaler's authorisation relates to an exempt sourced medicinal products, the authorisation holder shall only source such products —

17. (1) Where and insofar as the wholesaler's authorisation relates to an exempt medicinal product, the authorisation holder shall only source such product—

(a) in response to an order, or in anticipation of an order, which satisfies the requirements of paragraph 2 of Schedule 1 to the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007)*; and

(b) where the conditions set out in subparagraphs (2) to (9) are complied with.

(2) The authorisation holder shall, in the case of each consignment of an exempt medicinal product received by him or her, make, and keep available for inspection by officers of the Authority, for a period of not less than five years, written records showing the following particulars —

(a) the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the particular medicinal product is to be sold or supplied in the State;

(b) the dosage form;

(c) the trading style or name of the manufacturer of the medicinal product;

(d) in respect of each active constituent of the medicinal product, any international non-proprietary name or the monograph name or, where that constituent does not have an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of that constituent;

- (e) the quantity of medicinal product which has been received;
 - (f) the batch number of the medicinal product which has been received; and
 - (g) the name and address of the manufacturer of that medicinal product in the form in which it was received and, if the person who supplied the medicinal product is not the manufacturer, the name and address of such supplier.
- (3) Where the authorisation holder sells or supplies an exempt medicinal product, he or she shall, in addition to those records mentioned in paragraph 8(1) and subparagraph (2), make and maintain written records relating to —
- (a) the batch number of the batch of the product from which each sale or supply was made;
 - (b) details of any suspected adverse reaction to the product so sold or supplied of which he or she becomes aware; and
 - (c) details of any quality defect relating to the product so sold or supplied of which he or she becomes aware.
- (4) The authorisation holder shall not issue any advertisement, other than one that states only the trade name, pack size, price and dose, relating to an exempt medicinal product or make any representations in respect of such product.
- (5) The authorisation holder shall inform the Authority forthwith of any matter, including suspected adverse reactions and quality defects, coming to his or her attention, in respect of an exempt medicinal product that has been sourced by him or her.
- (6) The authorisation holder shall cease supplying an exempt medicinal product if he or she has received a notice in writing from the Authority directing that, as from a date specified in that notice, a particular product or class of products shall no longer be sourced or supplied.
- (7) The authorisation holder shall, on being informed by the Authority, or by the manufacturer or person who supplied the medicinal product to the holder of the authorisation, that the medicinal product cannot be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality or efficacy for such administration, immediately withdraw any supplies of that product held by him or her and immediately recall all supplies already sold or distributed.
- (8) With effect from the 1 January 2008, the authorisation holder shall, not later than seven days of his or her receipt of a consignment of an exempt medicinal product, notify the Authority of each such receipt. Each such notification shall include the particulars set out in subparagraph (2).
- (9) With effect from the 1 January 2009, the notifications referred to in subparagraph (8) shall, except in exceptional circumstances, be communicated electronically to the Authority and within a timeframe of two working days from the date of the receipt of each such consignment.
- (10) In this paragraph — ‘common name’ means the international non-proprietary name, or, if one does not exist, the usual common name; ‘international non-proprietary name’ means the international non-proprietary name recommended by the World Health Organisation; and ‘monograph name’ means the name or approved synonym which appears at the head of a monograph in the current edition of the European Pharmacopoeia, the British Pharmacopoeia, or a foreign or international compendium of standards and ‘current’ in this definition means current at the time the notice is sent to the Authority.
18. In paragraphs 3(1)(b) and (c), 4, 6(2)(b) and 13, every reference to a medicinal product shall be a reference to a medicinal product that is intended to be placed on the market in the State or in another EEA State.
19. (1) Subject to subparagraph (2), the authorisation holder shall verify that the medicinal products received are not falsified by checking any safety features on the outer packaging, in accordance with Regulation (EU) 2016/161.
- (2) Subparagraph (1) shall not apply where a medicinal product is directly received from a third country but not imported into the State.
20. The authorisation holder shall immediately inform the Authority and, where applicable, the holder of the relevant marketing authorisation, certificate of registration certificate of traditional-use registration, or in the case of a product intended for a state other than an EEA State the holder of the relevant authorisation in that state if he or she receives, is offered or sells by wholesale a medicinal product and he or she knows, or subsequently becomes aware after having sold by wholesale the product, or there are sufficient grounds to suspect, that the product is a falsified medicinal product.
21. Where a medicinal product is obtained from another wholesale distributor, the authorisation holder shall verify that the supplying wholesale distributor —
- (a) complies with the principles and guidelines of good distribution practice published by the Commission pursuant to Article 84 of the 2001 Directive, and
 - (b) holds a wholesaler’s authorisation, or an equivalent authorisation granted in another EEA State.
22. Where a medicinal product is obtained from a manufacturer or importer, the authorisation holder shall verify that the supplying manufacturer or importer holds an appropriate marketing authorisation, certificate of registration, certificate of traditional-use registration or in the case of a product obtained from a state other than an EEA State, the relevant authorisation issued in that state.
23. Where a medicinal product is obtained through brokering, the authorisation holder shall verify that the broker involved fulfils the requirements set out in these Regulations and the 2001 Directive.
24. (1) Notwithstanding anything to the contrary in these Regulations
- (a) until 31 December 2024, the Board shall allow the import of medicinal products from parts of the United Kingdom other than Northern Ireland by holders of a wholesaler’s authorisation that are not in possession of a relevant manufacturing authorisation following submission of a request by the holders of the marketing authorisation for the medicinal products provided that all of the following conditions are fulfilled—
 - (i) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 51(3) of the 2001 Directive, or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20, first paragraph, point (b) of the 2001 Directive,
 - (ii) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 51(1) of the 2001 Directive, or in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 51(1) of the 2001 Directive,
 - (iii) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union Law, by the Board or by the Commission,
 - (iv) the medicinal products are only made available to patients or end-consumers in the State, and
 - (v) the medicinal products bear the safety features referred to in Article 54, point (o) of the 2001 Directive.
- (2) Notwithstanding anything to the contrary in these Regulations, until 31 December 2024, Article 80, first subparagraph, point (b) of the 2001 Directive shall not apply to imports that fulfil the conditions laid down in paragraph (1).

This authorisation is subject to any other requirement specified as per the Medicinal Products (Control of Wholesale Distribution)

Health Products Regulatory Authority

Certificate No: 35646

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Ireland confirms the following:

The wholesale distributor (WDA): Pinewood Laboratories Limited

Site address: Unit 1, M50 Business Park, Ballymount Avenue, Dublin 12, D12 K6C5

OMS Identifiers: (ORG-100001380 / LOC-100007625)

Has been inspected under the national inspection programme in connection with authorisation number W00190/00002 in accordance with Art. 77(1) of Directive 2001/83/EC transposed in the following national legislation: Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538/2007), as amended

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2025-01-23, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2025-07-02

Name and signature of the authorised person of the
Competent Authority of Ireland

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Details of the authorisation can be found in the Union Database.

Health Products Regulatory Authority

Certificate No: 34467

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Art. 111(1) of Directive 2001/83/EC

The competent authority of Ireland confirms the following:

The wholesale distributor (WDA): Pinewood Laboratories Limited

Site address: Ballymacarbry, Clonmel, E91 D434, Ireland

OMS Identifiers: (ORG-100001380 / LOC-100000597)

Has been inspected under the national inspection programme in connection with authorisation number W00190/00003 in accordance with Art. 77(1) of Directive 2001/83/EC transposed in the following national legislation: Medicinal Products (Control of Wholesale Distribution) Regulations 2007 (S.I. No. 538/2007), as amended

Scope of certificate: Human medicinal products

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2024-04-23, it is considered that it complies with the Good Distribution Practice requirements laid down in Article 84 of Directive 2001/83/EC.

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

The authenticity of this certificate may be verified in the Union database. If it does not appear please contact the issuing authority.

2024-07-29

Name and signature of the authorised person of the
Competent Authority of Ireland

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Health Products Regulatory Authority
Confidential
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Details of the authorisation can be found in the Union Database.