Wockhardt Limited

Consolidated ESG Statement

FY 2024-25

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
Prohibition of Insider Trading Code 2024
Wockhardt Quality Policy
Wockhardt Cybersecurity Policy
Risk Management Policy
Prohibition of Insider Trading Code
Policy for Preservation of Documents
Forex Risk Management Policy
Code of Business Conduct and Ethics
Acceptable Usage Policy for IT Systems
Archival Policy
Anti-bribery and Anti-corruption policy
Anti-Trust and Fair Competition Policy
Business Responsibility and Sustainability Policy
Communications Policy
Code of Conduct for the members of the Board of Directors and Senior Management
Code of Conduct for Regulating, Monitoring and Reporting of Trading by Designated Persons
Corporate Social Responsibility Policy
Code for fair disclosure of Unpublished Price Sensitive Information
Diversity, Inclusion and Equal Opportunity Policy
Dividend Distribution Policy
Environment, Health, Safety & Sustainability Policy
Policy for Familiarisation Programmes for Independent Directors
Human Rights Policy
Policy for determining Material Subsidiaries
Policy on Related Party Transactions
Policy for determining materiality of events
Remuneration Policy
Stakeholders Relationship Policy
Template for Appointment of Independent Directors
Whistle Blower Policy

Link: https://www.wockhardt.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)	194,331.06
	Total Energy Consumed (in GJ)	657,964.04
	Renewable Energy Consumption %	29.54%
	Total Emissions Saved (tCO_2e)	32002.77

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 tracks and manages greenhouse gas (GHG) emissions across its global operations through data monitoring and targeted reduction initiatives. During the reporting period, the organization's total GHG emissions measured 1,40,352.57 MTCO2e, with Scope 1 emissions at 11,404.22 metric tons CO2e, Scope 2 emissions at 61,358.41 metric tons CO2e, and Scope 3 emissions at 67,589.94 metric tons CO2e. The climate action framework aligns with science-based targets, establishing objectives for net-zero emissions by 2050 and a 50% reduction in absolute emissions by 2030. The organization addresses Scope 2 emissions through renewable electricity implementation, with select facilities achieving complete transition to renewable power sources. The emissions management protocols for Scope 1 emissions incorporate fuel efficiency measures and alternative fuel adoption, supported by renewable energy infrastructure investments. The emissions tracking framework utilizes monitoring systems and reporting mechanisms that maintain alignment with international standards for climate action and environmental management requirements.

Table 2: Emission Data

Data Metrics	Sub metric	Values	Unit
Emission Data	Scope 1	11,404.22	tCO2e
	Scope 2	61,358.41	tCO2e
	Scope 3	67,589.94	tCO2e
	Total Scope 1 and Scope 2 emission intensity per rupee of turnover (Total Scope 1 and Scope 2 GHG emissions / Revenue from operations)	2.6	tCO2e/Mn.Rs
	Total Scope 3 emissions per rupee of turnover	2.4	tCO2e/Mn.Rs

Table 3: Biotech Briquettes Boilers Emission Data From Jan 2013 To Mar 2025

Jan 2013 To Mar 2025		
Savings at Biotech Park from Briquettes Boilers		
Data Metrics	**Values**	**Unit**
Carbon Emissions from Briquettes	4127.39	tCO2e
Carbon Emissions from FO	70739.16	tCO2e
Carbon Emissions Saved	66611.77	tCO2e
Total Savings in INR	689954690.00	Rs
Total Cost Savings in US Dollars ($)	8068701.79	$

Table 4: Shendra Briquettes Boilers Emission Data From Nov 2016 To Mar 2025.

Nov 2016 To Mar 2025		
Savings at Shendra from Briquettes Boilers		
Data Metrics	**Values**	**Unit**
Carbon Emissions from Briquettes	771.62	tCO2e
Carbon Emissions from FO	12294.49	tCO2e
Carbon Emissions Saved	11522.87	tCO2e
Total Savings in INR	71636621.00	Rs
Total Cost Savings in US Dollars ($)	837757.23	$

Key Performance Indicators

Table 5: Key Performance Indicators

Category	Metric	Wockhardt Group Level Value
Environmental Performance	Total Energy Consumption (in GJ)	657,964.04
	Renewable Energy Consumption (in GJ)	194,331.06
	Renewable Energy Consumption %	29.54%
	Avoided Emissions (in tCO_2e)	32,002.77 *
	Total Water Withdrawal (in kL)	858,580.05
	Total Waste Processed (in metric tonne)	5,854.01
	Waste Recycling Rate (%)	81.06%
	Total Scope 1 and Scope 2 Emissions (tCO2e)	72,762.63
	Scope 1 Emissions (tCO2e)	11,404.22
	Scope 2 Emissions (tCO2e)	61,358.41
	Total Water Withdrawal (in kilo liters)	858,615.58
	Water discharge by destination and level of treatment (in kilolitres)	303,258 kL Treated effluent sent to common effluent treatment plant (CETP)
	Rainwater Harvested	24 million litres
Social Metrics	Female Employee Representation (%)	18.29%
	ESG and Compliance Training Programs (count of programs annually)	213
	Employees Trained in ESG (%)	78.5%
	Critical Health and Safety Incidents	1

Category	Metric	Wockhardt Group Level Value
Governance Metrics	Regulatory Compliance	Full compliance with environmental and regulatory requirements. 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: ≈ 0.092 tCO_2e/GJ
India: ≈ 0.190 tCO_2e/GJ
UK: ≈ 0.060 tCO_2e/GJ

Water Consumption

Wockhardt Limited implements water management protocols across its operations as part of its manufacturing activities. During the reporting period, the total water withdrawal was 858,580.05 KL, primarily sourced from surface water (52.9%) and third-party water (32.2%), with smaller contributions from others (10.9%) and groundwater (4.0%). The Company's water management infrastructure incorporates closed-loop systems, process optimization measures, and treated wastewater utilization for landscaping and non-potable applications. The framework includes water audits and withdrawal source monitoring to maintain sustainable usage patterns, supported by wastewater treatment facilities that meet regulatory requirements. The organization tracks water intensity metrics and engages with communities on water resource access and ecosystem impact management. Additionally, rainwater harvesting contributed 24 million litres to overall water management efforts, further enhancing sustainability objectives.(Certificate in Appendix 4)

Table 6: Water Consumption Data

Data Metrics	Sub metric	Figures
Water Consumption Data	(i) Surface water (in kilolitres)	453,949
	(ii) Ground water (in kilolitres)	31,446.79
	(iii) Third Party Water (in kilolitres)	276,599
	(iv) Seawater / desalinated water (in kilolitres)	0
	(v) Others (in kilolitres)	96585.25
	Total volume of water withdrawal (in kilolitres) (i + ii + iii + iv + v)	858,580.05
	Total volume of water consumption (in kilolitres)	501,319.04
	Rainwater Harvested (in million litres)	24
	Water intensity per rupee of turnover (Total water consumption / Revenue from operations) (In kL/Mn Rs)	18
	Water discharge by destination and level of treatment (in kilolitres)	303,258 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)	5,854.01
	Recycling Rate	81.06%
	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
	Process Optimization	Measures in place to minimize waste generation
Environmental Impact	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 cover diverse areas such as ESG integration, POSH and business ethics, leadership development, functional skills, health and wellness, digital tools, and specialized technical training.

During the reporting year, Wockhardt Ltd conducted 142 training sessions for employees other than BoD and KMPs, with a total of 2,912 participants (1,049 male and 1,863 female), amounting to 919.7 training hours. The wide coverage reflects the Company's commitment to continuous employee development, compliance adherence, and value creation through knowledge sharing.

Table 9 : Training And Awareness Metrics

No. of Program	Programs	Male	Female	Participant Count	Total Hrs
13	POSH Compliance and Business Ethics	351	233	584	13
9	ESG Training	186	123	309	9
2	Pharmacovigilance	155	102	257	2
4	Excel Training	33	29	62	8
3	Competency Based Interviewing Skills	25	18	43	6
1	Emerging Young Leaders	14	1	15	3
1	Financial Webinar	17	14	31	2
1	Health Initiative - Bone Voyage & BMD Camp	72	54	126	2
1	Health Initiative - Your Health is your Priority	9	16	25	2
2	Visualization Dashboard	29	12	41	4
2	The 7 Habits of Highly Effective People	3	14	17	8
1	Negotiation Skills	52	2	54	2
1	AI training	15	9	24	2
3	Wockhardt Hospital Training	21	14	35	12
5	WOW	3	33	36	5
24	Sales Training Program	9	167	176	576
3	Regional Manager Developmental Program	2	86	88	240
47	LOGO Quiz	18	569	587	4.7
19	Refresher / Booster	35	367	402	19
142	Total	1049	1863	2912	919.7

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	1,200,000 INR
	Base Salary – Men	28,100,000 INR
	Base + Incentives – Women	1,100,000 INR
	Base + Incentives – Men	15,200,000 INR
Management Level Pay	Base Salary – Women	1,223,676 INR
	Base Salary – Men	1,105,053 INR
Non-Management Level Pay	Base Salary – Women	0 INR
	Base Salary – Men	309,219 INR
Gender Pay Gap	Mean Difference	Female(12.94%)Higher than Male
	Median Difference	Female (16.74%) higher than Male
	Mean bonus gap	20.74%
	Median bonus gap	21.40%

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	FY 2022	FY 2023	FY 2024
Total number of new employee hires	838	675	680	503
Percentage of open positions filled by internal candidates (internal hires)	12.3%	12.4%	7.6%	2%
Average hiring cost/FTE Currency: INR	0.074	0.069	0.068	0.086

Table 12 : Hiring – Data Breakdown (FY 2024)

Category	Sub-category	Number of Hires
Age Group	<25 years	102
	26–30 years	152
	31–35 years	118
	36–40 years	64
	41–45 years	35
	>45 years	32
Gender	Male	441
	Female	62
Management Level	Junior	439
	Middle	51
	Senior/Top	13

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.

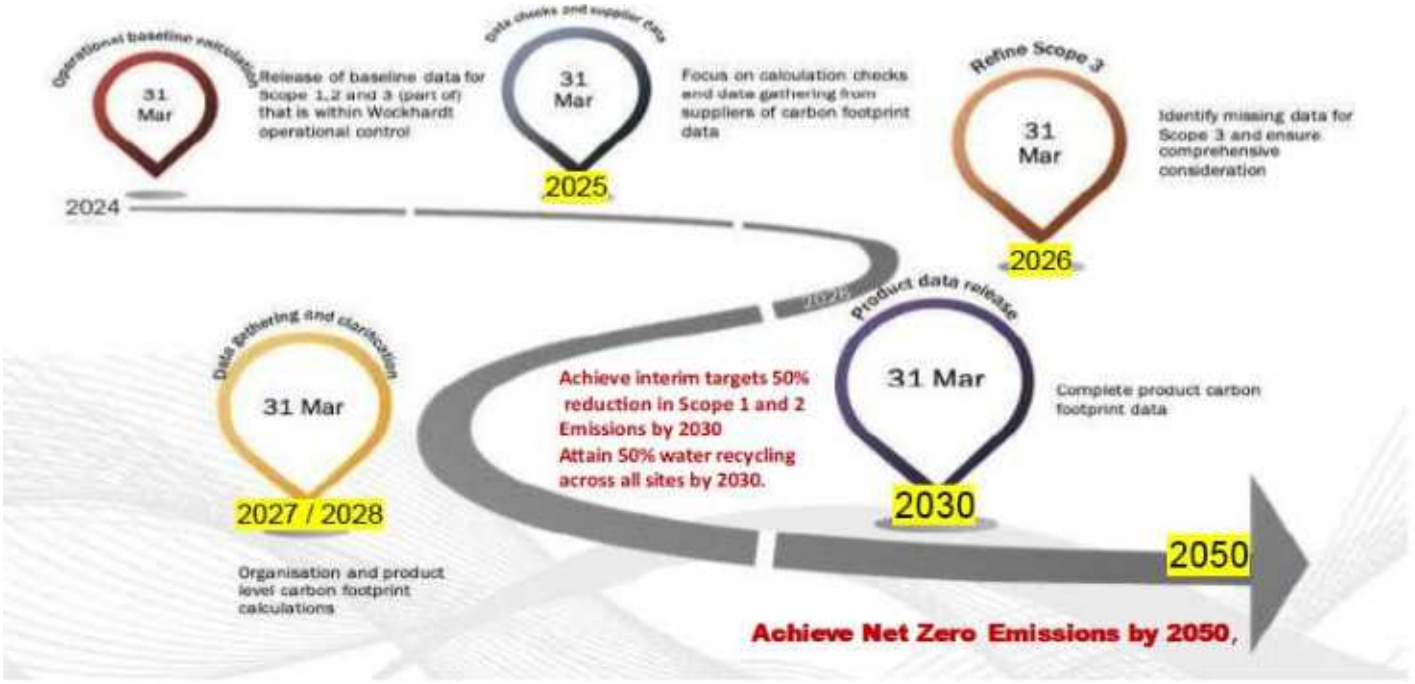
Key Strategic Focus Areas:

- 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

Operational Baseline Calculation — 2024

Release of baseline data for Scope 1, 2, and partial Scope 3 that is under operational control.

2025 — **Data Checks & Supplier Data**

Focus on verifying calculations and gathering data from suppliers to ensure accurate carbon data.

Refine Scope 3 — 2026

Identify missing data for Scope 3 and ensure comprehensive consideration of all relevant sources.

2027 — **Data Gathering & Clarification**

Consolidate organization-level and product-level carbon footprint calculations.

Product Data Release — 2028

Complete and release comprehensive product-level carbon footprint data.

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 CO_2 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 $CO_2 = 1$).

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_2O)	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 2024)	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 2025
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 2025 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

Scope 3 Category	Category Description	Minimum Boundary	Wockhardt Calculation
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), including retail and storage (in vehicles and facilities not owned or controlled by the reporting company)	The scope 1 and scope 2 emissions of transportation providers, distributors, and retailers 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	Transportation to distribution hub (3 in 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

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:

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.

3. Working hours and shift patterns
4. Workforce numbers

The organization now operates two business streams:

1. Vaccine
2. CP Hospital products

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

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 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%.

Short-Term Improvement Goal To Achieve A Reduction Of 10% For 2024/5 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 2025.

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 2024. There are some assumptions and average data that have been used and will be improved on during 2025. 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.

APPENDIX OVERVIEW

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Appendix 5	**Waste Management Certificates**
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Appendix 6	**Quality Assurance Certificates (GMP)**
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	- Daman Kadaiya
	- Ankleshwar
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APPENDIX 1:
Energy Conservation & Technology Absorption At Wockhardt Ltd
FY 2024 -2025

Annexure 1.

Energy & Water Conservation, Technology Absorption at Wockhardt Ltd in FY 2024 -25.

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 utilising alternate sources of energy and the Capital investment in energy conservation equipments:

ANKLESHWAR

1. The power factor maintained 0.989 (requirement 0.95 above), which leads to saving of ₹ 6.93 Lakh.
2. The high efficiency pump is installed at Cooling Tower pump, which leads to savings of 6 kW/hr.
3. Initiated to maintain the DO Dissolved Oxygen in aeration, installed CCox Agitator.

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. Replacement of V belt with flat belt system in phase wise manner.
3. Chiller's set point increased from 6.5 Deg. C to 7.0 Deg. C for reduction in power consumption. Energy Units saved 41,152 KWH, saved amount ₹ 2.46 Lakh.
4. 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 91171 KWH per year, amount saved ₹ 5.47 Lakh per year.
5. Installation of VFD in Finished Goods stores to Run AHU on 48.5 Hz in place of 50 Hz. Saved ₹ 1.29 Lakh per annum & Electrical Units saved 21,600 KWH per annum.
6. 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 week day and holiday. Total Electric units saved 197,164 KWH per year. Amount saved ₹ 11.82 Lakh per year.
7. Earlier AHU was running on 24 hours now as per area requirement of production plan, AHU Operation system (ON/OFF) is implemented and saving electrical units. Energy Units Saved 83,340 KWH and amount saved ₹ 5.0 Lakh in a year.
8. Phase wise replacement of old low efficiency motor with high efficiency motors.
9. Heater has been replaced with hot gas coil to avoid chiller operation on weekly day and holiday and saving by consumption is ₹ 2.90 Lakh per year.

Water System area

1. 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 8.8KL water and amount saved ₹ 1.18 Lakh for 4 months in a year.
2. Purified rejected water used cooling tower and steam condensate has been used in boiler water instead of Soft water. Saved water 34.56 KL and saved ₹ 4.60 Lakh per year.
3. UF water used for gardening purpose, saved water 16.5 KL and saved ₹ 2.64 Lakh.
4. RO water has been used for wash room (raw water), water saved 30.0 KL and amount saved ₹ 4.80 Lakh.

Utility area

1. Utilized low capacity 35 CFM air compressor for water system in place of 505 CFM air Compressor on plant off days and Holidays, saving by consumption and saved energy units 148148 KWh and amount ₹ 8.88 Lakh saved.
2. Reduced loading & unloading pressure of compressed air system and achieved electrical unit saving by 3%. Energy Units saved 18720 KWH and amount ₹ 1.12 Lakh per year.
3. Reduced Boiler operating pressure and achieved fuel consumption up to 3%, fuel in liters saved 1120 Ltrs and amount saved ₹ 0.60 Lakh per year.
4. CFL Lamps replaced by LED lamps in phase wise manner.

5. 36 Watt LED light replaced with 18 watts LED light in plant all area and achieved saving in electrical unit. Energy Units saved 247,898 KWH and amount saved ₹ 14.87 Lakh.
6. Street light - CFL Lamps has been replaced by LED lamps and achieved saving in electrical unit.
7. Power factor has been maintained through auto operation capacitor bank with unity power factor.
8. Motion sensor has been installed on Air curtain to avoid continues operation and saved electrical unit. Energy Units saved 64.8 KWH and amount saved ₹ 3,000/-.
9. Total 115,179 KWH solar units generated at Kadaiya plant from April, 2024 to March, 2025 from renewable solar energy.

SHENDRA

1. Electricity demand reduced to minimize the Electricity Bill by ₹ 30 Lakh / Year saved.
2. Power factor maintained close to unity (0.999), resulting in cost saving ₹ 7 Lakh per year with energy units saved 50,000 Kwh per year.
3. Local vendor developed for repairing of electronic PCB & control systems, reducing cost by 50% compared to outside vendors saved amount ₹ 3.5 Lakh per year.
4. Terminal Sterilizer along with pump connected to UPS to avoid DG Operation for critical Emrok TS Loads. Diesel cost reduced by ₹ 5.00 Lakh energy units saved 20,000 Kwh /year.
5. AHUs of Warehouse area are kept OFF during no activity which result in saving of ₹ 4 Lakh/year and energy units savings of 35,000 kwh per year.
6. ETP water used for gardening 26.8 Million ltr/year.
7. 80% condensate recovery from plant to Boiler Feed water tank. 4.5 million Litre reused/year.

R & D CENTRE

1. EPO lab AHU kept off and run only when batch is planned in area. Saved 67,200 unit per year and saved amount ₹ 8.06 Lakhs per year.
2. AHU kept off in night time from 06:00 pm to 08:00 am and Saved 50,400 unit per year and 0.30 Lakhs per year saved. Biotech Main Lab - USP – AHU kept off from - 6.00 pm to 8.00 am – 14 hrs per day.
3. 100 TR Trane chiller Evaporator chemical descaling done to achieve better approach i.e. below 3 Deg. Cel. (Load on 60%). By reducing with 2 Deg. C 5 % energy saving done, saved 2520 KWH units per year amount saved ₹ 0.35 Lakhs.
4. Diabetic area- Lab AHU kept off and run only when batch is planned in area.
5. 90 TR (45 Tr Twin compressor) chiller installed in PDS building instead of 160 TR. We used L1 plant idle chiller instead of new procurement.
6. R&D area all three chiller interlock with each other and kept one chiller off in night time. Save energy by keeping Cooling tower off, for this cooling tower we off water pump which have capacity of 10 kw, also cooling fan of cooling tower capacity is 7.5 kw for 14 Hours. Saved 58,800 units per year, amount saved ₹ 7.06 Lakhs per year.
7. Pharma FRD area AHU kept off in night time from 06:00 pm to 08:00 am, Saved 50400 KWH units per year, amount saved ₹ 6.05 Lakhs per year.
8. R&D area main Air compressor 310 cfm kept off in night & run small compressor in night time for biotech area batch. By using small compressor saved 7,680 KWH units per year, amount saved ₹ 0.92 Lakhs per year.
9. AHU, Vacuum pump regular Preventive Maintenance for better efficiency & performance.
10. Injection area - Lab AHU kept off and run only when batch is planned in area.
11. PDL Bldg, R&D Bldg and Animal house chillers, chilled water pipeline interconnected, to share the load in night time & keep R&D building chiller OFF.
12. AHU NO 04 off Disso lab and office area replaced chilled water coil by new for better efficiency.
13. Steam supplied by running low capacity 600 Kg/hr instead of 800 kg/hr Boiler.
14. LED Fixture fitted for all street light Pole, instead of sodium vapour lamp. Replaced 150 watt with 100 watt. Total number of light is 70. from this we save approx. 33 % energy i.e. (150watt-100watt=50watt saving) (50 watt*70 nos. of lights = 3.5 kw). For 12 Hrs we save 42 KW, Saved 15,330 units per year and ₹ 1.84 Lakhs saved per year.
15. Regular periodical preventive maintenance of transformer, DG set, air compressor chillers, cooling towers, split air conditioners done for better efficiency.
16. Capacitor Bank - periodical Preventive Maintenance.
17. Cassette AC - repairing and servicing done with replacement of new control card, blower motors for DRA & AVL department for better performance of AC units on CPB building 1st Floor.
18. NDD Biology department - Walk in Cold room - Refrigeration system replaced by new and done hot standby unit of same capacity, for better efficiency.
19. Offices/Laboratory Lights /Air conditioners - switched off manually, whenever not required and in night period.
20. Replaced defective 165 TR chiller, in PDS building, with idle 90 TR chiller from L-1 site. We used old, idle 90 TR chiller from L-1 unit, instead of new Capex procurement. Approximately saved ₹ 35 Lakh by using idle chiller instead of new Capex procurement.

BIOTECH PARK

EOU OSD

1. Air compressor capacity 223 CFM replaced in Jan. 24 instead of earlier 600 CFM. Resulting 250 unit saving per day amount saved ₹ 10 Lakh /Year.
2. Reduction in on roll manpower by 20 % and replace with Contractual labours to fulfil market requirement resulting cost saving.
3. Power factor maintained close to unity (0.999), resulting in cost saving ₹ 4 Lakh per year.
4. RM 2 warehouse AHU keep OFF and utilised RM 1 resulting ₹ 4 Lakh saving.
5. Large FG warehouse AHU keep OFF and shift all finished goods in small FG warehouse as per requirement resulting ₹ 2 Lakh saving.

API

1. Maintain Unity PF (0.999) & saved unit in Electricity bill saved ₹ 15 Lakhs / month.
2. SV lamp replaced with LED lamp saved energy 1,800 units/year (25 Nos of 70 Watt SV replaced with 50 w LED flood lights for 10 hrs running) 1,880 KWH units saved.
3. Chiller No 4 & 9 condenser descaling done - 390 units / day saved total 142,350 KWH units saved.
4. At E-coli product change over switch of Old Utility system one pump of CT pump, Sec Pump, Pri pump & CT fan (55+45+22+11KW) save @ 121kw /Hr for three months 261,360 KWH units saved.
5. At E-coli product change over switch of New Utility system one pump of CT pump, Sec Pump, Pri pump & CT fan (55+45+18+15KW) save @ 133kw /Hr for three months 287,280 KWH units saved.
6. Cooling water Pump Modification done Pump Impeller trimming done found 5 Kw/hr saving in each Pump So KW X 3 Nos Pumps =15 Kw/Hr (15 KW X 24 X 365 days) means total @ ₹ 13.14 Lakhs saving done 131,400 KWH unit.
7. Cooling tower - Cooling fan operation control in auto mode by temperature controller to maintain required temperature to chiller refrigerant cooling - 26 to 29 Deg. centigrade.

(B) TECHNOLOGY ABSORPTION, ADAPTATION AND INNOVATION:

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

FORMULATION-2

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.

APPENDIX 2: Renewable Energy Certificates

(Renewable Energy Certificate)

Shell ENERGY

RENEWABLE ELECTRICITY CERTIFICATE

Awarded to

C P PHARMACEUTICALS LIMITED

100% of the power supplied by Shell Energy UK Limited from 01/07/2022 to 30/06/2025 will have an equivalent number of certificates purchased from renewable schemes.

Signed on behalf of Shell Energy UK Limited:

Greg Kavanagh
Sales Director

21/03/2024
Date

H22062035789434
Document number

100% renewable energy

2010.00159

APPENDIX 3:
ISO Certificates

Certificat

(ISO Certificates)

Certificate

N° 2018/79819.3

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**

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.

Certificat

Certificate

N° 2018/79820.5

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)
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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.

Certificate IN24/00000540

The management system of

Wockhardt Ltd.

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

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

APPENDIX 4:
Rain Water Harvesting Certificate

Varsha-Jal™
rainwater harvesting

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.**

Vijay Kedia
Authorised Signatory

The Grown Water

APPENDIX 5:
Waste Management Certificates

Packaging Waste Recovery

Member No: **100783**

REPAK
Business *funding* recycling

CERTIFICATE OF COMPLIANCE

2024

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

Pinewood Laboratories Limited
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

Séamus Clancy
Chief Executive Officer, Repak

TEAM GREEN

QF 030a v4

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	

Einarnation
breathing life into a greener future
E-Incarnation Recycling Pvt. Ltd.

Tel : 022 66251300-33
Email : info@e-incarnation.com
Web : www.e-incarnation.com
CIN No. : U51101MH2010PTC210228

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

E-INCARNATION RECYCLING PVT LTD Mumbai

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 KURLA COMPLEX, BANDRA EAST, MUMBAI - 400051.

Section A: Materials Received for processing

ERPL Customer Id: 585 Transaction Id: 1507

Materials Received	Quantity
AS PER LIST	—

Mumbai

Eincarnation
breathing life into a greener future
E-Incarnation Recycling Pvt. Ltd.

Tel : 022 66251300-33
Email : info@e-incarnation.com
Web : www.e-incarnation.com
CIN No. : U51101MH2010PTC210228

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

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
Thineclient	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.

E-INCARNATION RECYCLING PVT. LTD. Mumbai

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**

HI 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 of 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.

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.

APPENDIX 6: Quality Assurance Certificates (GMP)

MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

CERTIFICATE OF GOOD PRACTICES FOR INPUTS MANUFACTURING ACTIVE PHARMACEUTICALS

BIOLOGICAL ACTIVE PHARMACEUTICAL INPUTS LINE

The National Health Surveillance Agency - ANVISA, through Resolution RE No. **1.218,** of **04/06/2023,** published in the Federal Official Gazette (DOU) on **04/10/2023,** certifies that the company below is periodically inspected and monitored by the National Sanitary Surveillance System and which complies with the guidelines for Good Manufacturing Practices 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, Aurangabad 431136, Maharashtra State Country: India Single Code:

A.000631 Requestor: Farma Vision Importação e Exportação de Medicamentos Ltda CNPJ:

09.058.502/0001-48 Imprint

(s): 4820592/22-0 Certificate of Good Manufacturing Practices for Active Pharmaceutical Ingredients: Biological active pharmaceutical ingredients: insulin glargine.

This certification is valid until 04/10/2025 **and** may be canceled if the competent health authority proves non-compliance with the requirements established by the current rules of Good Practice.

Document electronically signed by **Ana Carolina Moreira Marino Araujo, General Manager of Sanitary Inspection and Surveillance,** on 04/10/2023, at 12:35 pm, according to official Brasília time, based on § 3 of art. 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 checked on the website https://sei.anvisa.gov.br/autenticidade, informing the verification code **2332134** and the CRC code **56940EB9.**

(Daman Bhimpore)

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 licencee 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

LICENSING AUTHORITY
लाइसेन्सिंग प्राधिकारी
Daman
U.T. OF DAMAN & DIU

(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

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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 **Е.Г. Приезжева**

м.п.

06 сентября 2023 г.
(дата выдачи сертификата)

☒ **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

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	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 **Е.Г. Приезжева**

М.П.

06 сентября 2023 г.
(дата выдачи сертификата)

	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

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	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 _____ **Е.Г. Приезжева**

06 сентября 2023 г.
(дата выдачи сертификата)

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

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4. ПРОЧИЕ ОПЕРАЦИИ - ФАРМАЦЕВТИЧЕСКИЕ СУБСТАНЦИИ

Ограничения или пояснительные заметки, касающиеся области применения сертификата: -

Заместитель Министра **Е.Г. Приезжева**

06 сентября 2023 г.
(дата выдачи сертификата)

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).

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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

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

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	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

	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

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

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

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.

Medicines & Healthcare products Regulatory Agency

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

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

	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

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

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.

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY U.T. of Dadra & Nagar Haveli and Daman & Diu

(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 AND DIU
ASSISTANT DRUGS CONTROLLER (I/C) &
LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE
MOTI DAMAN-396 220

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NO. DCD/D&D/LA/2023-2024/6833 DATED: 03/07/2023.

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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.

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY U.T. of Dadra & Nagar Haveli and Daman & Diu

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

(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

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NO. DCD/D&D/LA/2022-2023/ 3035 DATED: 17/03/2023

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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

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NO. DCD/D&D/LA/2022-2023/ 3036 DATED: 17/03/2023

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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:
17 MAR 2023

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY U.T. of Dadra & Nagar Haveli and Daman & Diu

(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(5) 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**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

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 8913/376537-0008[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. DCD/D&D/LA/2023-2024/12074
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.
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 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).

(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/2023-2024/12075 DATED: 16 /12/2023

SCHEDULE M - G.M.P CERTIFICATE

THIS IS TO CERTIFY THAT **M/S. 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 CATEGORY OF 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.

ASSISTANT DRUGS CONTROLLER & LICENSING AUTHORITY U.T. of Dadra & Nagar Haveli and Daman & Diu सहायक औषधि नियंत्रक एवं लाइसेंस प्राधिकारी सत्यमेव जयते

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.

(Ankleshwar)

EudraGMDP

MIA | GMP | APIREG | IMPA | GDP | Sites Help

Wed 13 Dec 2023 10:20:18 BST

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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/ECis 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***

No: WHO-GMP/22043238/ /B 24389
Commissioner
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block No.8, 1st floor, Gandhinagar
Date :

12 APR 2022

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 : 08/12/2021

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/22043238/2022/ /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. : **22043238**

On the basis of the inspection carried out on **24-25/01/2022 & 01/04/2022** *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 (APIs)	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 **07/04/2025** *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

Email : *comfdca@gujarat.gov.in*

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

Date : *08/04/2022*

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

COMMISSIONER FOOD & DRUGS CONTROL ADMINISTRATION • GANDHINAGAR • GUJARAT STATE

WOCKHARDT | LIFE WINS

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

Upendra Upadhyay
Authorized Signatory

For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

8 APR 2022 To 7 APR 2025

Contd..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. (a)	Sitagliptin Phosphate	IH
(b)	Sitagliptin Phosphate	USP
16. (a)	Deferasirox	IH
(b)	Deferasirox	EP

For Wockhardt Limited

Upendra Upadhyay
Authorized Signatory

For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

8 APR 2022 To 7 APR 2025

COPY

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

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)

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

GMP Certificates

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.

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**
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	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: +91-22-2659236[illegible]
Fax: +91-22-2659195[illegible]
1COW945126891[illegible]
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

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

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Valid until: 10/16/2025

Published on the Brazilian Official Gazette – Resolution – RE n.º: 3.908, on: 10/16/2023

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

Document electronically issued at: 12:18:12 on 10/19/2023 (Date/Brasilia Time Zone - UTC/GMT -3 hours)

Safety Control Code: XRSQ.GH05.FBMA.A8NW.9VE3.T1FT.INY7.MWJJ.NPN2.P32G

Check the authenticity on: http://www9.anvisa.gov.br/Peticionamento/validarcertificadoBPF_BPDA/

308439

DRUG

NATIONAL AUTHORITY

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.

NATIONAL DRUG AUTHORITY
02 SEP 2022
PLOT 19 LUMUMBA AVENUE
P. O. BOX 24576 KAMPALA

Denis Mwesigwa
FOR THE AUTHORITY

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.

MINISTRY of HEALTH of the **REPUBLIC of TURKEY**

TURKİSH MEDİCİNES AND MEDİCAL DEVİCES 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.

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 Kalemi (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.

MINISTRY of HEALTH of the **REPUBLIC of TURKEY**

TURKİSH MEDİCİNES AND MEDİCAL DEVİCES AGENCY

CERTIFICATE of GOOD MANUFACTURING PRACTICE

Certificate Number: 2024-201/1	Date of certificate: 23.05.2024
Product Name(s):	Glaritus Dispopen 100IU/mL Solution for injection in a pre-filled pen (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 releases process
Inspection date:	08-11.08.2023

Within the scope of subparagraph A (on-site inspection) of the "Guideline on 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.

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.

274590

DRUG

NATIONAL **AUTHORITY**

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.

NATIONAL DRUG AUTHORITY
27 OCT 2023
PLOT 6 LUMUMBA AVENUE

Denis Mwesigwa
FOR THE AUTHORITY

MINISTRY OF HEALTH

BRAZILIAN HEALTH REGULATORY AGENCY

GOOD MANUFACTURING PRACTICES CERTIFICATE

Issued by Automatic Renewal foreseen in RDC 39/2013

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, AURANGABAD 431136, MAHARASHTRA STATE

AURANGABAD

ÍNDIA

Manufacturing Lines:

1) Steriles: Aseptically Processed Small Volume Parenteral Solutions

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Valid until: 04/10/2025

Published on the Brazilian Official Gazette – Resolution – RE n.º: 1.212, on: 04/10/2023

Requested by: FARMA VISION IMPORTAÇÃO E EXPORTAÇÃO DE MEDICAMENTOS LTDA, **CNPJ:** 09.058.502/0001-48

Document electronically issued at: 07:16:16 on 04/11/2023 (Date/Brasilia Time Zone - UTC/GMT -3 hours)

Safety Control Code: PLRD.YV35.KKTP.UWEJ.2NIB.JU7S.QK5P.Y9A3.NVLT.SS7B

Check the authenticity on: http://www9.anvisa.gov.br/Peticionamento/validarcertificadoBPF_BPDA/

BADAN POM

BADAN PENGAWAS OBAT DAN MAKANAN

Jl. Percetakan Negara No. 23 Jakarta Pusat 10560 Indonesia
Telp. (021) 4244755, 4245459, 42883309, 42883462, 42883279; Fax : (021) 4247496
Email : infopom@indo.net.id; Website : www.pom.go.id

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 Produsen	:	Biotech Park, H-14/2, M.I.D.C, Waluj, Aurangabad, Maharshtra – 431 136, 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

FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :-02 Aug 2022

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/113905/2022/11/41623**

On the basis of the inspection carried out on **30.05.2022 and 31.05.2022** ,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 AURANGABAD 431136 MAHARASHTRA STATE, INDIA**
2. Licence No. : **AD004 In Form 28D**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	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 01 Aug 2025 . 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
1COW5171390520220802
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 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.

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Joint Commissioner (H.Q.)
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.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1COW51711390520220802
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/113905/2022/11/41623

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:**02 Aug 2022**

FOOD AND DRUGS ADMINISTRATION COMMISSIONERATE MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 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

COMMISSIONER, FOOD AND DRUG ADMINISTRATION MAHARASHTRA STATE

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 filled with UltraSafe Passive Needle Guard

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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
1COW51711390520220802
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11/41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 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: With HSA Stabilizer Aqueous Buffer qs Pack: 0.5 ml Pre-filled Syringe filled with UltraSafe Passive Needle Guard Erythropoietin Concentrated Solution IP 2000 IU
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 ...

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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
1COW51711390520220802
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/113905/2022/11/41623

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:**02 Aug 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11/41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 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 Ph.Eur 4000 IU With HSA Stabilizer Aqueous Buffer qs Pack: 0.4 ml Pre-filled Syringe filled 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 filled 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 filled 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

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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
1COW51711390520220802
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 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
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

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

Name of the Authorised person : **D. R. GAHANE**

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Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:02 Aug 2022

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11/41623 **VALID UP TO :01 Aug 2025**

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BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 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

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Name of the Authorised person : **D. R. GAHANE**

Signature :

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Food & Drug Administration, M.S.
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Maharashtra State, India
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COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

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
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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Name of the Authorised person : **D. R. GAHANE**

Signature :

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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AURANGABAD 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

1 2 3 4 5 6 7 8 9 10 ...

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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ICOW5171139052022080 2
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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
AURANGABAD 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	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.
72	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 Injections IP qs One unit of sterile Disposable needle provided to be used with Glaritus Dispopen Pack: Dispopen containing 3 ml cartridge.

1 2 3 4 5 6 7 8 9 10 ...

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Name of the Authorised person : **D. R. GAHANE**

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
73	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.
74	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.
75	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
76	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
77	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
78	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
79	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
80	GLARITUS Insulin Glargine 100IU/mL Solution for Injection	Each mL of Cartridge Contains: Insulin Glargine (rDNA) 100 IU m-cresol USP 0.27 % w/v Water for Injection USP QS Pack: 3 ml Cartridge

1 2 3 4 5 6 7 8 9 10 ...

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
81	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
82	GLARITUS Insulina Glargina (recombinant DNA origin) Recombinant Insulin Glargine Injection 100 IU/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 IU of Insulin Glargine (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Pack: 3 ml cartridge
83	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.
84	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.
85	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
86	Glaritus 100 IU/mL Insulin Glargine Injection BP 100 IU/mL (Recombinant DNA origin)	Each mL contains: Insulin Glargine 100 IU m-Cresol (as preservative) 0.27 % w/v Water for Injection qs Pack : 10 ml Vial
87	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
88	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

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INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
89	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
90	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
91	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
92	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
93	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
94	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
95	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 Each ml contains: Insulin Glargine 100 IU (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin Pack: 10 ml vial, 3 ml cartridge
96	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.

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
97	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
98	GLARITUS DISPOPEN 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
99	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
100	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
101	GLARITUS DISPOPEN Insulina Glargina (Recombinant DNA origin) Recombinant Insulin Glargine Injection 100 IU/mL Solution for 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 3 ml Each ml contains 100 IU of Insulin Glargine (equivalent to 3.64 mg) corresponding to 100 IU of Human Insulin 1 unit of sterile Disposable needle provided to be used with this product Pack: Dispopen containing 3 ml cartridge

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

102	GLARITUS DISPOPEN Insulina Glargina (Recombinant DNA Origin) Recombinant Insulin Glargine Injection 100 IU/mL Solution for 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 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.
103	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 One unit of sterile disposable needle provided to be used with Glaritus Dispopen Pack : Dispopen containing 3 mL Cartridge
104	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.

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Name of the Authorised person : **D. R. GAHANE**

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LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
105	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
106	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
107	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
108	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
109	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
110	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
111	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
112	INSULINA 30/70 Insulina Isofena 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.

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Sr.No.	Name of the Product	Composition
113	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
114	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.
115	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.
116	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.
117	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.
118	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
119	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
120	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

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Name of the Authorised person : **D. R. GAHANE**

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Sr.No.	Name of the Product	Composition
121	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
122	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
123	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
124	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
125	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
126	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.
127	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.
128	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

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Name of the Authorised person : **D. R. GAHANE**

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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
129	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
130	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
131	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.
132	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
133	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
134	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
135	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
136	Wepox 30000 Recombinant Human Erythropoietin Injection 30000 IU (Recombinant DNA origin)	Each 3mL Cartridge for pen contains Erythropoietin Concentrated Solution Ph.Eur 30000 IU Benzyl Alcohol Ph.Eur. (As preservative) With HSA Stabilizer Aqueous Buffer Q.S. Pack: 3mL Multi-dose Cartridge

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Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
137	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
138	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
139	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
140	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
141	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
142	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
143	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
144	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

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Sr.No.	Name of the Product	Composition
145	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.
146	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.
147	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.
148	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.
149	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 filled with UltraSafe Passive Needle Guard
150	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
151	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
152	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

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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
1COW5171139052022080 2
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
153	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
154	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
155	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
156	WEPOX-2000 Recombinant Human Erythropoietin Injection 2000 IU Solution for Injection	Each 0.5 mL pre filled syringe contains; Recombinant Human Erythropoietin 2000 IU With HSA as stabilizer. Pack: pre filled syringe
157	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
158	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
159	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
160	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

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
161	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
162	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
163	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
164	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
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 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
166	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 & 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
167	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

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION, MAHARASHTRA STATE

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

168	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

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT
/AD/113905/2022/11/41623

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:**02 Aug 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
169	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
170	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 USP 40 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 vial.
171	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
172	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
173	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
174	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 % v/v Water for Injection USP qs Pack: 10 ml vial
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 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

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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

176	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

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:**02 Aug 2022**

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
177	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: 10 ml, 5 ml vial.
178	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.
179	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 & 3 ml Cartridges. & Penfills & Pre filled Syringes
180	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 : 10 mL Vial, 5ml Vial & 3ml Vial
181	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
182	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.
183	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
184	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.

... 17 18 19 20 21 22 23 24 25 26

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:02 Aug 2022

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/AD/113905/2022/11 /41623 **VALID UP TO :01 Aug 2025**

Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
185	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
186	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
187	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
188	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
189	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
190	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
191	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
192	WOSULIN-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% 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.

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WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:02 Aug 2022

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
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INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
193	WOSULIN-50/50 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 (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.
194	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.
195	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.
196	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.
197	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.
198	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.
199	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.
200	WOSULIN-R Insulina Humana 100 IU/mL Regular Human Insulin of recombinant DNA Origin. Injectable soultion	One 10 mL vial contains; 1000 IU of Regular Human Insulin of recombinant DNA origin. Pack: 10 ml vial.

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COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

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Name of Manufacturing Firm : WOCKHARDT LIMITED
BIOTECH PARK, H-14/2, MIDC WALUJ
AURANGABAD 431136 MAHARASHTRA STATE,
INDIA

Drug License No : AD004 In Form 28D

Sr.No.	Name of the Product	Composition
201	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
202	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.
203	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.
204	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.
205	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.
206	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.
207	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.

... 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
1COW51711390520220802
WOCKHARDT LIMITED - NEW-WHO-GMP/CERT /AD/113905/2022/11/41623

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:02 Aug 2022

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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. 3° 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. 1° 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 BOLÓGICOS** 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	Liquidos	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.

Instituto Nacional de Vigilancia de Medicamentos y Alimentos - Invima
Oficina Principal: Cra 10 N° 64 - 28 - Bogotá
Administrativo: Cra 10 N° 64 - 60
(60)(1) 742 2121
www.invima.gov.co

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* ***RENUEVA*** *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 cárpules de vidrio.
PRODUCTO BIOLÓGICO (Origen: Recombinante en Levadura: Hansenulla polymorpha): Insulina humana Isofana	Líquidos	Suspensiones parenterales de pequeño volumen en viales y cárpules de vidrio.
PRODUCTOS BIOLÓGICOS (De origen de recombinante en E. Coli): Insulina Glargina	Líquidos	Soluciones parenterales de pequeño volumen en viales y cárpules 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 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 cárpules 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 frio.*
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 criticas 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."*

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: Hansenulla polymorpha): Insulina humana Regular	Líquidos	Soluciones parenterales de pequeño volumen en viales y cárpules de vidrio.
PRODUCTO BIOLÓGICO (Origen: Recombinante en Levadura: Hansenulla polymorpha): Insulina humana Isofana	Líquidos	Suspensiones parenterales de pequeño volumen en viales y cárpules de vidrio.
PRODUCTOS BIOLÓGICOS (De origen de recombinante en E. Coli): Insulina Glargina	Líquidos	Soluciones parenterales de pequeño volumen en viales y cárpules 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

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 cárpules 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 frio.
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.) FIPAR; 12/04/2022, Revisión Técnica: G. Hernández (Q.F.) [illegible]. Vo.Bo. E. Neira. Coordinadora GTM
Revisión Legal: E. Téllez (Abogada) ETZ, Archivo: Exp Nro. 360E.

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 Kalemi (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.

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 Kalemi (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 ürünün/ürünlerin varsa ilgili kılavuz çerçevesince denetimi gerekli diğer üretim aşamalarının gerçekleştirildiği tesisler için düzenlenmiş olan GMP belgeleri ile birlikte geçerlidir.

FDA MAHARASHTRA

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**

COMMISSIONER FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

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 GMP[1]

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 GMP[1]

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
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 GMP[1]

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
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)	

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
1COW0471358782024081 4
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**

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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis 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**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 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
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
	1.5.1 Primary Packaging 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**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

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***

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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) 2017/1569 [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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis 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

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

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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'

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)

1	**MANUFACTURING OPERATIONS**
	1.2 Non-sterile Products
	1.2.1 Non-sterile products (processing operations for the following dosage forms)
	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
	1.2.2 Batch Certification
	1.5 Packaging
	1.5.1 Primary Packing
	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
	1.5.2 Secondary Packing
	1.6 Quality control testing
	1.6.2 Microbiological ; Non Sterility
	1.6.3 Chemical / Physical

Any restrictions or clarifying remarks related to the scope of Manufacturing operations (for registered users)

1.2 includes the manufacture of hormonal products.

ADDRESS(ES) OF CONTRACT MANUFACTURING SITES ANNEX 3

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

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. Colum Honan

Qualifications: Bachelor of Engineering, Professional Certificate in Management, Professional Diploma in Management

DATE OF INSPECTION WHICH AUTHORISATION GRANTED ANNEX 7

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)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

1	**MANUFACTURING OPERATIONS**
	1.2 Non-sterile Products *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 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 *1.2.2 Batch Certification* **1.5 Packaging** *1.5.1 Primary Packing* 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 *1.5.2 Secondary Packing* **1.6 Quality control testing** *1.6.2 Microbiological ; Non Sterility* *1.6.3 Chemical / Physical*

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 Microbiological ; Non Sterility
	2.1.3 Chemical / Physical
	2.2 Batch certification of imported medicinal products
	2.2.2 Non-sterile products
	2.3 Other importation activities
	2.3.1 Site of physical importation

SCOPE OF AUTHORISATION(Investigational Medicinal Products) ANNEX 2

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 *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.1 Capsules, Hard Shell 1.2.1.17 Other non-sterile medicinal product - Powders **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.1 Capsules, Hard Shell *1.5.2 Secondary Packing*

Name and address of the site: **Chanelle Medical Ireland Limited, Loughrea, Co. Galway, Ireland**

1	**MANUFACTURING OPERATIONS**
	1.2 Non-sterile Products *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.13 Tablets **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.13 Tablets *1.5.2 Secondary Packing*

1	**MANUFACTURING OPERATIONS**
	1.5 Packaging *1.5.2 Secondary Packing*

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 *1.4.3 Other - Storage/Site of Physical Importation*

Name and address of the site: **Dexcel Limited, 1 Dexcel Street, Or Akiva, 3060000, Israel**

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 **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.1 Capsules, Hard Shell *1.5.2 Secondary Packing*

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 *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.13 Tablets **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.13 Tablets *1.5.2 Secondary Packing*

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 *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.13 Tablets **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.13 Tablets *1.5.2 Secondary Packing*

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 *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.13 Tablets **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.13 Tablets *1.5.2 Secondary Packing*

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 *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.13 Tablets **1.5 Packaging** *1.5.1 Primary Packing* 1.5.1.13 Tablets *1.5.2 Secondary Packing*

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 Laboratory:	**Flavine Pharma France**
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

DATE OF INSPECTION WHICH AUTHORISATION GRANTED ANNEX 7

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 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 patents 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)

Regulations 2007 (S.I. No. 538 of 2007)*. *as amended

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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	Paulina Nulty
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
	2.3.1 Site of physical importation

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.

SCOPE OF AUTHORISATION(Investigational Medicinal Products) ANNEX 2

This annex is not applicable

ADDRESS(ES) OF CONTRACT MANUFACTURING SITES

ANNEX 3

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

DATE OF INSPECTION WHICH AUTHORISATION GRANTED ANNEX 7

This annex is not applicable

PRODUCTS AUTHORISED FOR IMPORT
ANNEX 8

This annex is not applicable

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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 Niamh O'Donnell

9. Date of authorisation **14 May 2025**

10. Annexes attached

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 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 patents 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)

Regulations 2007 (S.I. No. 538 of 2007)*. *as amended

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

Confidential

Health Products Regulatory Authority
Confidential

Confidential

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

Confidential

Health Products Regulatory Authority
Confidential

Confidential

Details of the authorisation can be found in the Union Database.