FACILITY: WOCKHARDT, WOCKHARDT India

Standard Operating Procedure

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1.0 PURPOSE:

To describe the procedure for initiation/logging, assessment, investigation, approval, closure, tracking and trending of market complaints.

2.0 SCOPE:

This procedure is applicable to the complaints received against marketed drug substances and drug products manufactured at Wockhardt India.

All Third Party organizations (TPOs) conducting activities on behalf of Wockhardt, India must have SOP in place to manage market complaints and should commensurate with the expectations and requirements contained within this SOP. In case of market complaint with respect to product manufactured at All Third Party organizations (TPOs) procedure SOP **WI-CQ-S0127** shall be followed.

3.0 RESPONSIBILITY:

3.1 Initiator:

- To initiate and record the Market complaint within one calendar day after receipt. If Market complaint cannot be initiated within one calendar day, then rationale must be included in the record to justify the delay.
- To acknowledge the receipt of complaint within three (3) calendar days through proper mode of communication (like electronic-mail/fax etc.)
- To collect relevant information (which may help in investigation and impact assessment) from the complainant through appropriate communication channel.
- To review the market complaint and take immediate actions, as appropriate. To provide any additional support as requested by the Market Complaint Coordinator.

3.2 Market complaint Coordinator:

- To perform initial and final quality assessment and classify the market complaint.
- To review, evaluate the market complaint and comment.
- To keep track of completion and closure of market complaint and trending.
- To take appropriate actions for closure of market complaint.
- To identify the SME (Subject Matter Expert) for Investigation and cross functional team, if any.
- To log the Market complaint and Assign Number for Market complaint and to verify Log for closure in case of exigency.
- To request for complaint/Retention sample analysis, if required.
- To perform trending of market complaint.

3.3 Subject Matter Expert (SME):

- To evaluate and comment on the market complaint.

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- To review investigation findings and CAPA of similar incidences for repetitive market complaints.
- To manage the market complaint/investigation until its completion.
- To conduct the investigation. Identify cross-functional SMEs, if necessary to assist with investigation.
- To track associated tasks until completion.
- To document the findings.
- To identify the cause(s), definitive or probable.
- To initiate the CAPA
- To develop a CAPA plan (if required) appropriate to the market complaint and investigation findings.
- To ensure the market complaint/investigation is complete and accurate.

3.4 Department Head(s):

- To review investigation for completeness and accuracy.
- To participate in investigation, as required.
- To ensure the investigation is performed with the goal of determining the root/probable cause of the market complaint using appropriate investigative tools and techniques.
- To support timely closure of market complaints
- To confirm accuracy and adequacy of CAPA measures proposed by SME and/or Quality Unit
- To implement interim measures to ensure conditions responsible for market complaint do not persist while CAPA measures are being implemented

3.5 Site Head:

- To review adequacy of investigation and CAPA for Critical Market complaints.

3.6 Quality Head (or designee):

- To final evaluation of market complaint and risk ranking.
- To review of investigation findings and CAPA of similar incidences for repetitive market complaints.
- To make determination, if any field actions are required (Field Alerts and/or Recall) and to ensure timely notification of the appropriate regulatory body, as applicable
- To review, Critical and Major Market complaints. Also Minor market complaints, if recommended for Investigation.
- To approve the Request for extension of timeline for closure of market complaint.

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- To cancel market complaint, if market complaint is created in error or if there is sufficient rationale for cancellation (e.g. Duplicate initiation).
- To approve the re-opening of a record, when required.

Note: Quality Head role shall be allocated to Site Quality Head or person authorized by Site Quality Head.

4.0 ACCOUNTABILITY:

Site Quality Heads are accountable for implementation and compliance of the SOP at their respective sites.

5.0 DEFINITIONS:

5.1 **Market complaint:** A product complaint is defined as an expression of dissatisfaction conveyed about a product/batch through verbal, written or electronic communication in relation to the identity, quality, durability, reliability, safety, effectiveness or performance of a drug product, drug substance (API), after distribution to Market for public consumption.

5.2 **Quality Complaints** - A quality complaint is any report indicating a possible deviation from the product specification (i.e. changes in, or deterioration of, the physical and/or chemical characteristics of the product or packaging). These reports may concern the packaging, labeling, medical devices, or drug product.

5.3 **Adverse events:** An adverse events can therefore be any unfavorable and unintended sign, symptom, or disease temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product

5.4 **Lack of effect:** It is appropriate to classify a report as Lack of Effect when a complaint specifically states that the drug was ineffective or when the information reported clearly communicates that the expected effect was not obtained, but “Lack of Effect” was not specifically reported.

5.5 **Repetitive Market complaint:** A market complaint which has an occurrence of 3 times in 12 months having similar issue/event/problem on same product / process is considered to be repetitive market complaint.

5.6 **Genuine:** A complaint where the investigation, indicates the reported defect occurred or likely to occur due to any intended or un intended activity or non-conformance at any of the functions of Wockhardt India.

5.7 **Non-Genuine:** A complaint where the investigation, complaint sample, etc. indicates the reported defect did not occur under manufacturer’s control.

5.8 **Counterfeit:** Counterfeit Products: A drug product, drug substance, or biologics which is deliberately and fraudulently mislabeled with respect to identity and / or source. Counterfeit product may include products with the correct ingredients, with the wrong ingredients, without active ingredients, with an insufficient quantity of active ingredients or with fake packaging.

5.9 **Overdue Market Complaints:** All Market Complaint which is not closed within SOP defined period.

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5.10 **Temperature Excursion:** A temperature excursion is a deviation from the approved storage conditions for a product for a certain period of time, either during storage or transport.
Or
An excursion event in which a product is exposed to temperatures outside the range(s) prescribed for storage and/or transport. Temperature ranges for storage and transport may be the same or different; they are determined by the product manufacturer, based on stability data.

6.0 **PROCEDURE:**

6.1 **General Instructions:**

6.1.1 Principle and business rule for Market Complaint is defined in this SOP. System operating procedure for Market Complaint record is defined in SOP No. **WI-CQ-S0169**. Market complaint process is explained through Flow chart in **WICQS0008-A01**.

6.1.2 Market complaint process comprises of following activities.

- Market complaint initiation
- Initial Quality Assessment (Risk Assessment and classification)
- PVG communication in case of ADR/ADE / LOE
- Regulatory communication assessment (Only for critical and Major Market complaints)
- Extended Investigation (Market complaints classified as critical, major and Minor- Cause Not Identified)
- Final Quality Assessment (Risk Assessment, Impact assessment and Final classification)
- SME Approval and CAPA submission
- SME HOD Approval
- CFT Approval
- Closure Review
- Site Head Approval (for Critical Market complaint)
- Quality Head Approval (for Major and Critical Market complaint)
- Record Closure

6.1.3 Following precautions shall be taken while using EQMS (Trackwise) system for Market Complaint.

6.1.3.1 Initiator having multiple site access shall select the site where the concerned product is manufactured. In case initiator has inadvertently selected the wrong plant / site name then Market complaint Coordinator shall reject the market complaint during Initial Quality Assessment.

6.1.3.2 In EQMS (Trackwise) system, mandatory fields for each activity are indicated with red arrow and records will not move to next stage unless or mandatory fields are attempted.

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6.1.3.3 EQMS (Trackwise) System has Provision to attach supporting documents of any type i.e. Microsoft office documents, portable document format (PDF), pictures, images, layouts, auto cad files, videos, audio files, etc.

6.1.3.4 Users shall ensure Supporting documents which are required to be attached to the Market Complaint at different stages shall be identified appropriately with relevant file name. Reference Market Complaint PR/ QMS number shall be indicated on all supporting documents and same shall be retained as per predefined procedure.

6.1.3.5 User shall intermittently save the record, while carrying out documentation in EQMS (Trackwise) System.

6.1.3.6 For all stages where record can be sent back to previous stage, comment in activity summary is mandatory. Reason for record send back shall be recorded in activity summary.

6.1.3.7 Care shall be taken to ensure that one person is selected for one role within a single record.

6.1.3.8 Responsible stage owners can be re-selected by user who has selected the owner, if required. However Initiator can be re-selected only by a user having 'Default Quality Head' role in the system. Re-selection of persons selected as Cross Functional Team member cannot be changed by any user. Any such requirement shall be addressed through raising Operational Issue form as per SOP **WI-IT-S0014**.

Note: Default Quality Head role shall be assigned to the Quality Head or his designee.

6.1.4 Complaints may be received from customers, Regulatory agencies, Qualified Persons and any other associates through mail, postal/ courier, Phone, Fax, and any other suitable means of communication.

6.1.5 Temperature excursion during transit should be registered as Complaint. In case of US products manufacturing sites, applicable site SOP should be followed to handle such situations.

6.1.6 Complaint handling for products specifically manufactured for clinical trial must be described in a study protocol, technical agreement, or other appropriate documents.

6.1.7 Market complaints which are identified as adverse event (ADR/ ADE) shall be forwarded to the responsible Pharma Covigilance Unit for evaluation.

6.1.8 If sufficient information is not received as a matter of due diligence, Market Complaint Coordinator shall make attempts by appropriate means, to contact the Complainant. Depending on criticality or seriousness of complaint, the attempts made to reach the complainant shall be addressed in the response report with appropriate evidence.

6.1.9 Complaints of Critical nature shall be communicated to Corporate Quality Head for information/ guidance.

6.1.10 All market complaint shall be closed within predefined timeline. If any delay in the closure for market complaint, extension shall be initiated and approved before due date of the market complaint. For any extension request, appropriate justification shall be provided specifying which activity cannot or couldn't be completed within the scheduled closure due and the reason

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for not completing the activity. Justification shall also include impact of delay in completion of the particular activity/action.
The rationale for extending a market complaint must be based on the necessity to gather additional information necessary to reach the appropriate root cause or to identify other information critical to the closure of the market complaint.

6.2 Market complaint Initiation (Initiator from Site QA):

6.2.1 On receipt of any market complaint, initiator shall raise market complaint in Trackwise within one (1) calendar day from the market complaint receipt and shall acknowledge the receipt of complaint within three (3) calendar days through proper mode of communication (like electronic-mail / fax, etc.). Copy of acknowledgment can be attached as supporting document in file attachment. Refer SOP **WI-CQ-S0169** for details of system operating procedure for market complaint initiation.

Note1: For acknowledgement of complaint, initiator can generate crystal report from Trackwise and send to the complainant through proper mode of communication (like electronic-mail / fax, etc.).

Note2: Complaint Initiation shall be done by any person identified from QA function. For products marketed in US, market complaint can be initiated by identified person from Wockhardt US or respective manufacturing site quality.

6.2.2 Recipient / initiator shall take all measures to retain / preserve samples / evidences and associated documents (e.g. Complaint received in written form) which will assist in investigation.

6.2.3 Initiator shall fill the below mentioned information during initiation of Market complaint.

Note: PR No. and QMS Record No. shall be generated by the system after saving and submission of record respectively. Refer point No. 6.2.6 for logic of Market complaint QMS record number. Minimum Information which are required for saving the record and generation of PR number are marked with '*' mark. Minimum Information which are required for submission of market complaint record for initial quality assessment are marked with '**' mark. Information which is conditional is marked with '#' mark. Information which are not marked either with '*', '**', '#' are additional information and shall be recorded if relevant to the market complaint.

6.2.3.1 **Short Description *:** Initiator shall describe the complaint received in a concise manner and shall include key words that are factual, meaningful and most relevant to the Market Complaint so as to facilitate easy identification and retrieval of the record.

6.2.3.2 **Date of Receipt of Complaint *:** Enter the date when market complaint was received. Ensure that the selected date is correct and is either past or current date. In case date of complaint received is prior to one calendar day from the date of initiation, Initiator shall provide appropriate justification for the delay in market complaint record initiation against 'Justification for delay' field.

6.2.3.3 **Source of Complaint ***: Initiator shall select appropriate source of market complaint to indicate market complaint has been received from either Regulatory Agency/ MOH, Customer/Consumer, QP, Associates, MAH, Trader, Distributor, Physician, Pharmacist, Other

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health professional, Lawyer, Other Manufacturer, etc. If the market complaint is received other than specified above, initiator shall select 'Other'.

6.2.3.4 **Source of Complaint if Others #:** If 'Source of Complaint' is selected as 'Other' then details shall be provided in this section.

6.2.3.5 **Nature of Complaint *:** Based on the complaint received the initiator shall appropriately select the nature of complaint from the options available. If initiator finds nature of complaint other than those mentioned, initiator shall select 'Others'

6.2.3.6 **Nature of Complaint if Others #:** If 'Nature of Complaint' is selected as others, details for the nature of complaint shall be provided in this section.

6.2.3.7 **Complaint Category *:** Initiator shall appropriately select the category of complaint indicating the category with respect to Quality Complaint / Loss of Effect / Adverse Drug Reaction / Adverse Drug Effect based on complaint received.

6.2.3.8 **Name of Complainant **:** Initiator shall write the name of complainant against the field provided for the name of complainant. If name of complainant is not available name of regulatory agency / mail id / shall be requested and same shall be mentioned.

6.2.3.9 **Address of Complainant **:** Initiator shall mention address of the complainant from where the complaint has been received against the field provided.

6.2.3.10 **Initial Reported by **:** Write the name of person who initially reported the complaint.

6.2.3.11 **Mode of Complaint Receipt **:** Initiator shall select appropriate option to indicate the mode of communication such as Phone / Fax / Email / Post through which the complaint was received, if compliant is received by any other mode 'Others' shall be selected and details regarding it shall be provided against field 'Other mode of comp. receipt'.

6.2.3.12 **Email Address / Fax **:** If mode of complaint receipt, is selected as either Email / Fax, complete mail address or Fax number shall be recorded against this field for further communication.

6.2.3.13 **Phone Number **:** If mode of complaint receipt, is selected as Phone, complete phone number shall be recorded against this field for further communication.

6.2.3.14 **Product / Drug Info Details:** Initiator shall record all relevant information such as Product name & Strength, Customer, Market , Batch / Lot Number, Product Code, NDC, Manufacturing date, Expiry / Retest Date, Pack size, Quantity affected, etc. about the product for which complaint has been received.

6.2.3.15 **Description of Complaint **:** Initiator shall briefly describe about the complaint along with relevant information received. Additional information available with respect to complaint shall also be mentioned here so as to facilitate further investigation.

6.2.3.16 **Due Date and Revised Due Date:** Due date and revised due date shall be auto generated by system based on generation of record and approval of extension respectively.

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6.2.3.17 **PVG Communication Initiated #:** If complaint is categorized as ADR/ADE / LOE, field 'PVG Communication Initiated?' becomes mandatory and initiator may decide to initiate PVG communication

6.2.3.18 **Market Complaint Coordinator **:** Initiator shall appropriately select the name of responsible person as market complaint coordinator for further review and assessment of the complaint.

6.2.4 All supporting documents shall be attached in the 'File Attachment' by Initiator.

Note: Initiator shall mention 'Not Applicable' along with appropriate justification against fields which are marked as '*', '**' if information are not relevant to the market complaint.

6.2.5 Initiator shall sign off the record electronically and submit the record for further Initial Quality assessment. If complaint is categorized as ADR / ADE / LOE, initiator shall open record and if desired, may create an action item as part of PVG communication and finally submit for Initial Quality Assessment by signing off electronically.

6.2.6 On submission of the market complaint record, system shall allocate QMS record number and Market complaint Closure due date as per predefined logic.

QMS Record number shall be :
MC/XX/YYYY– NNN
Where,
MC stands for Market complaint,
XX stands for Facility Code or Division (Refer **SOP WI-CQ-S0001),**
YYYY indicates current calendar year,
NNN indicates serial number assigned to market complaint in 3 digits.
Example: QMS record number for first market complaint of 2020 at Shendra shall be numbered as MC / SH / 2020-001.

6.3 Initial Quality Assessment (Market Complaint Coordinator (MCC)):

6.3.1 Market complaint Coordinator shall review, all the details recorded as part of market complaint initiation including the information provided through the attachments (if any). Based on the review, market complaint coordinator shall decide to submit the record for further processing or send back to initiator for additional information required. If any additional information is required, coordinator shall mention appropriate comment in activity summary to send back record to initiator.
During initial assessment, Market complaint coordinator (MCC) shall evaluate the nature and severity of complaint and need of extending investigation to other batches of same product and other products. MCC shall document the assessment in assessment summary.

6.3.1.1 **Complaint Sample:** Market Complaint Coordinator has to verify the complaint received and receipt of complaint sample along with it. Based on the availability of the sample along with complaint, coordinator shall select the appropriate value as Received / Not Received and if sample is not required along with complaint, coordinator shall select Not Required. If sample is received affix label on complaint sample as per Annexure **WICQS0008-A10**.

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6.3.1.2 **Complaint Sample Received Date:** If complaint sample is available for the respective complaint, coordinator shall mention the date of receipt of the sample. Selected date cannot be future date, it shall be either past or current date.

6.3.1.3 **Date Sample Requested:** If complaint sample is required and not received, same shall be requested. Date when the request for the complaint sample was sent shall be mentioned for this field.

6.3.1.4 **Photograph Received:** Based on type of complaint, coordinator shall decide for requirement of photograph and based on availability of photograph, coordinator shall select appropriate value as YES / NO.

6.3.2 **Risk Assessment**: Based on the information available, the Market complaint Coordinator shall perform a risk assessment through evaluation of occurrence, severity and detection for the reported Market Complaint.

6.3.2.1 Market complaint Coordinator shall Refer **SOP WI-CQ-S0012** for Quality Risk Management.

6.3.2.2 **Occurrence**: In order to assess occurrence level (Low, medium, High), Market complaint coordinator shall review Complaint records of past 12 months. As a general guideline 1 market complaints in 12 months shall be considered as Low Occurrence, 2 market complaints in 12 months as Medium Occurrence and 3 or greater number of market complaints in 12 months as High Occurrence. Where EQMS system has market complaint data for last 12 months, relevant market complaints can be identified by running queries. The queries may include product name/ batch number, nature of complaint or other key parameters related to the market complaint.

6.3.2.3 **Severity**: Shall record risk or threat the Market complaint may pose to patient safety, product quality like potency, strength etc. and decide severity level (Low, medium, High). As a general, guideline market complaint which may pose serious health consequence, risk to patient safety or serious quality impact on drug product or drug substance (for example lifesaving drug product / drug substance used for life saving product) shall be considered as High. Severity for market complaint of drug substance shall be assessed irrespective of its distribution status in market. Market complaint which may pose product quality impact (if not a lifesaving product) or may have reversible health consequences shall be considered as Medium. Market complaint that does not pose any risk to patient safety or impact on product quality and are related to product / product component/ packaging, leading to inconvenience in usage and storage etc. shall be considered as low.

6.3.2.4 **Detection**: Shall record details of existing measures/controls to detect reported defects or the impact of such defect. These controls might be automated, mechanized, procedural, multipoint verification etc. As a general guideline detection level of controls or measures those are certain or highly likely to detect the defect or cause of the defect shall be considered as high (e.g.: automated alarms, interlocks, real time data capture and publishing etc.). Detection level of controls or measures those are likely to detect the defect or cause of the defect shall be considered as medium (e.g.: Indicators, gauges, visual inspections, doer checker system, any other procedural control etc.). Detection level of controls or measures those are likely to miss identification of defect or cause of defect shall be considered as low (e.g.: lack or cumbersome of procedural control, inadequate verification frequency, etc.)

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6.3.3 **Market complaint Initial Classification**: Based upon the selected values for occurrence, severity and detection details, the system will populate initial classification (Minor – cause identified / Minor – cause not identified / Major / Critical) for the market complaint as per predefined logic. Where more than one option is available, select the most appropriate classification based on the information available. See Annexure **WICQS0008-A02** for the classification grid based on the occurrence, severity, detection values.
Market complaint which may pose serious health consequence, risk to patient safety must be classified as Critical.

Note: Market complaint which may pose serious health consequence, risk to patient safety and quality of product like potency and strength etc. which required immediate action from complaint owner must be classified as Critical". Market complaints having minimal impact and the cause is obvious as derived from information provided during initiation shall be classified as Minor- cause identified. Market complaints having minimal impact but the cause of market complaint is not obvious as derived from information provided during initiation shall be classified as Minor- cause not identified.

6.3.4 **Assessment Summary:** Requirement to hold complaint batch/(es) or impacted batch/(es) (if still within Wockhardt control) shall be assessed by Market Complaint Coordinator. Market complaint coordinator shall communicate such requirement to appropriate stakeholder. The Market complaint Coordinator shall summarize assessment performed, actions taken, communications made within this section and record justification in support of the classification. Any Additional comments regarding the market complaint can also be recorded under this field.

6.3.4.1 During initial assessment, Market complaint co-ordinator shall evaluate the nature and severity of complaint and need of extending investigation to other batches of same product and other products shall be assessed.

6.3.5 If the market complaint is classified as Minor- cause identified, then final assessment, final impact assessment and final classification shall be done by market complaint coordinator.

6.3.6 **Selection of Subject Matter Expert (SME):** Market complaint coordinator shall select the person having adequate expertise in the area of market complaint who shall be responsible for investigation. SME selection is required for Market complaints classified as Minor- cause not identified, Major and Critical. For market complaints classified as minor-cause identified, SME selection is not required.

6.3.7 **Selection of Quality Head:** Market complaint coordinator shall select the Quality Head if the market complaint is classified as Major or Critical in order to assess the requirement of Regulatory authority notification/communication or any action on marketed product. For market complaints classified as minor- cause identified or minor- cause not identified, Quality Head selection is not required.

6.3.8 **Attachment by Market complaint Coordinator:**

6.3.8.1 If any document/s which can support initial Quality Assessment and further decision making, shall be attached with Market complaint by market complaint coordinator.

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6.3.8.2 Market complaint coordinator shall sign-off the record electronically, if record is to be submitted for further processing. On submission of record, it shall move to Quality Head Assessment in case of 'major' or 'critical' classification, or shall move to Investigation (SME) stage in case of 'minor- cause not identified' classification or shall move to final quality assessment in case of 'minor- cause identified' classification.

6.4 Quality Head Assessment:

6.4.1 For major and critical market complaint, Quality Head shall check the requirement for any regulatory communication including notification to QP/customer/ MAH as applicable or action to be taken on marketed products and accordingly select the YES / NO against 'FAR/Regulatory escalation required'. Quality head shall record justification for decision made with respect to Regulatory escalation requirement against 'Justification for decision'. If any actions are required to be taken with respect to this Quality Head may generate an 'Action Item' to trigger and track any action relevant to Regulatory escalation. Detailed procedure for Field Alert shall be followed as per the respective SOP of Field Alert.

Note: Scenario in which notification to management shall be considered as per SOP **WI-CQ-S0013**, Following types of complaint shall be considered but not limited to:

- Product Mislabeled
- Bacterial or other contamination
- Significant Chemical, Physical, or other change
- Deterioration of the distributed product
- Other Critical event

6.4.2 Quality head shall verify the details provided during initiation and initial quality assessment performed. Based on the evaluation he/ she shall decide to proceed the record for investigation by SME or return the record to the Market complaint Coordinator for additional information, for reassessment of classification, or reassignment of SME.

6.4.3 Quality head shall sign-off the record electronically, if record is to be submitted for investigation. On submission of record, record shall move to Investigation by SME stage in case of 'Minor- Cause Not Identified', 'major' or 'critical' classification,
If any additional information is required from Market complaint coordinator, Quality Head shall mention appropriate comment in activity summary to send back record to Market complaint Coordinator.

6.5 Extended Investigation: All market complaints which are classified as Critical, Major and Minor- Cause Not Identified, shall undergo Extended investigation stage. SME shall evaluate the data provided during initiation and market complaint coordinator assessment. If information provided is not adequate to facilitate investigation, SME shall send the record back to market complaint coordinator and appropriate remark shall be entered in activity summary. If information provided is adequate, SME shall perform investigation for identification of root cause / most probable root cause and impact of the cause.

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6.5.1 **Packaging:** If complaint sample is received, investigator shall verify the type of packaging done for the sample and appropriately select the type as Original pack / Pharmacy Vial. If the packaging is other than these types investigator shall select 'Others'.

6.5.2 **Packaging, If Others:** If packaging is selected as others, describe the packaging type of the complaint sample received against this field.

6.5.3 **Description of Complaint Sample:** Investigator shall describe in detail about complaint sample received including condition of the packaging.

6.5.4 **Quantity Received in Complaint:** Based on the complaint received or from the data collected from complainant, investigator shall mention the total quantity of sample for which complaint has been made.

6.5.5 Additional information relevant to complaint received which can facilitate the investigation or can give clarity about complaint shall be mentioned against the field 'Others, if any'.
Any follow-ups done with complainant regarding missing information / sample requirement / photograph / additional information, shall be recorded in field 'Follow-up Information'.
Documents, if any, supporting the complaint sample information shall be attached to 'File Attachment (Sample)'

6.6 Investigation details:

6.6.1 SME shall initiate investigation by recording details of investigation plan, team members required to be involved in investigation and shall specify the tool to be used for investigation. After mentioning the details SME shall save the record and initiate investigation with other team members. For tools that can be used refer applicable investigation SOP. During the course of investigation, appropriate documentation, as applicable, shall be carried out by SME or investigation team member. All documents shall be indicated with PR No/QMS number of market complaint and shall be signed–off by persons involved in the investigation. If investigation plan includes multiple activities, SME shall record investigation performed and outcome after completion of each activity.

Note: SME may choose to directly record details of investigation performed under this section.

6.6.1.1 While preparing investigation plan, SME shall review recommendations given by Market complaint coordinator with respect to extension of investigation to other batches of same product and other products. The investigation plan shall include review of previous market complaints, deviations, change controls, CAPAs filed in past to identify any linkage / association with the complaint. Period for which this evaluation shall be performed is not limited to previous 12 months. Depending on the nature and severity of complaint, the scope of investigation may be extended upto pervious 3 years or till shelf life (whichever is more) of the product. Rationale for period selected, products / batches considered for investigation shall be documented as part of investigation either under investigation details section or within each of six areas of discrepancies available under root cause analysis section.

Note: During course of investigation, if the requirement of regulatory communication or action (Field Alert/Recall etc.) then immediately notify to the Head of Quality to carry out the same. This regulatory communication or action should be recorded while final assessment.

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If required, the marketing authorization holder (MAH) of particular country (Wockhardt/Partner/Agent/CNF) shall extend the investigation of the complaint up to stockiest or distributor level to ensure, there no similar nature of complaint for same lots.

6.6.2 A general guidance for assessment / investigation based on type of complaint is provided in **WICQS0008-A03** and can be used in conjunction with the aspects mentioned under section 'Root Cause Analysis'. The investigation activities shall not be limited to those listed in **WICQS0008-A03**.

6.6.3 **Investigation for Counterfeit Product:** In case of any market complaint related to counterfeit or suspected counterfeit a known, genuine sample i.e.: Reserve sample shall be considered for reference and investigation. Investigation for such complaint shall include following aspects but not limited to:

6.6.3.1 Check for existing controls like:

- Batch Number
- Any distinct mark
- Coding details
- Version no. of pack
- 2D codes
- Barcode
- Shade of Packing material
- Color of ink of text matter

6.6.3.2 The packaging materials should be examined first, starting from the outside and working inwards. Wherever required help of Packaging development shall be obtained for investigation.

6.6.3.3 At the end of packing material examination, if required, the suspected counterfeit sample should be chemically analyzed and compared against the results of chemical analysis of the reserve sample and the results should be reported.

6.6.3.4 All suspected counterfeit samples should be suitably identified and securely handled and stored to ensure that there is no possibility of a mix-up.

6.6.4 Reserve / Retention Sample Examinations:

6.6.4.1 Examination of the Reserve / Retention sample (Control Sample) shall be performed, as appropriate, based on the nature of the complaint reported.

6.6.4.2 Visual Inspection of the reserve / retention sample shall be carried and documentation of the visual inspection should include the following:

- Sample Appearance - Product Name, Description and Condition of the Reserve/ Retention Sample.
- Packaging Appearance - The condition of the packaging components.

6.6.4.3 The need for analytical, physical, and/or microbiological testing other than Physical Appearance and Description testing (e.g., assay, dissolution etc.) on the Reserve/ Retention sample (along with quantity of sample required) needs to be evaluated and approved by

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Quality Head based on the information obtained during the investigation.

6.6.4.4 Wherever reserve sample is required for analysis or verification as a part of complaint Investigation, adequate sample shall be withdrawn from reserve sample after approval of request as per Annexure **WICQS0008-A04,** while withdrawing sample it shall be ensured sample population covers entire batch run.

6.6.5 Examination of Complaint Sample:

6.6.5.1 All received complaint samples shall be evaluated as a part of investigation.

6.6.5.2 Complaint sample shall not be subjected to any chemical testing as a part of routine investigation. Testing of complaint sample shall be performed only after approval by Quality Head.

6.6.6 Wherever investigation warrants for analysis for a specific test or all tests of retention/ reserve/ complaint sample shall be proposed as per annexure **WICQS0008-A04**.

6.7 Root Cause Analysis: SME shall capture or record evaluation performed with respect to personnel discrepancy, material discrepancy, equipment discrepancy, procedural discrepancy, process discrepancy, environmental discrepancy against respective fields and shall select YES / NO for each of above.
Following aspects shall be considered to identify discrepancy that could have led to the reported Market Complaint.

6.7.1 **Personnel Discrepancies**: The Investigator will determine the impact of personnel on market complaint:

- Did personnel follow written procedures (SOPs, Batch Records, Work Instructions, etc.)?
- Were personnel appropriately trained on procedure, equipment/instrument, or process? Was training documented and sufficient to perform the activities as required?
- Were personnel aware of the defect before, during, or after the release of the complaint batch? Did personnel take any actions before, during or after the release of complaint batch to mitigate or exacerbate the defect?
- Was there appropriate oversight of personnel by management?

6.7.2 **Material Discrepancies**: The Investigator will determine the impact of materials on market complaint:

- Did all materials meet specifications prior to or following processing?
- Have materials satisfactorily been used in other conforming batches of product?
- If materials were accepted without fully testing (COA and ID testing) is additional testing required to ensure the materials meet specifications? If yes, what testing and what were the results? If no, what was the rationale?
- Was the vendor/supplier contacted for additional information regarding the material? Was the vendor/supplier notified about the defect for reported complaint?
- Was there any potential impact on material previously manufactured or currently in-process?

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Detail rationale explaining impact on previous materials particularly those which have been released.

- Are there additional materials (e.g. intermediates) which could be impacted by the market complaints?

6.7.3 **Equipment Discrepancies**: The Investigator will determine the impact of equipment on market complaint:

- What equipment/instrumentation was involved? This section should include all potential equipment/instrumentation involved including measuring/monitoring units.
- Was equipment in good working order before, during and after the market complaint?
- Was equipment/instrumentation properly calibrated and within calibration period? Was calibration range appropriate for range of actual use? Is/was additional testing/recalibration performed on the equipment/instrumentation to ensure it was functioning properly?
- Was equipment/instrumentation of the right type, size, and material of construction to perform the required task?
- Was equipment/instrumentation used on any previous batches which could be impacted?

6.7.4 **Procedural Discrepancies**: The Investigator will determine the impact of procedures on market complaint:

- Were there written procedures for the task being performed? (SOPs, work instructions, batch records, compendia monographs, etc.)
- Were the written procedures clear and unambiguous?
- Were procedures easily accessible to personnel?
- Had procedures been recently updated or significantly modified?
- Had the procedure been executed successfully previously?

6.7.5 **Process Discrepancy:** The Investigator will determine the impact of the process on market complaint:

- Had process been executed successfully previously?
- Has process been validated or qualified?
- Were all the parameters for the process within expected/historical range?

6.7.6 **Environmental Discrepancy:** The Investigator will determine the impact of the environmental conditions on the market complaint:

- Were temperature and humidity conditions within normal or acceptable range for the activities being conducted?
- Were utilities (water, air systems, nitrogen, etc.) systems functioning properly?
- Was housekeeping in the area optimal or was the area cluttered?
- Was personnel fatigue a factor?

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SME shall ensure that the details provided for each discrepancy supports the YES / NO value selected.

Apart from above aspects other investigation details can be recorded against 'Other investigational details' field.

6.7.7 SME shall indicate whether root cause is identified or not by selecting YES / NO value. SME shall record the root cause or most probable root cause, if 'YES' value is selected. If there is "No Root Cause" or "No Probable Root Cause" found, justification for the same shall be provided. For list of root cause and root cause sub-category refer annexure **WICQS0008-A05**. All supporting documents shall be attached the investigation documents.

6.8 **CAPA Plan:** Based on the outcome of the investigation and evaluation of immediate action taken, SME shall indicate whether a Corrective and Preventive actions (CAPA) is required or not by selecting YES / NO value. The Investigator shall propose CAPA based on the root cause / probable root cause identified or provide justification for no CAPA requirement.

6.9 **Final Quality Assessment (Market complaint Coordinator):** Final quality assessment shall be done by the Market complaint Coordinator. During the assessment, Market complaint Coordinator shall assess the investigation performed, root cause identified and CAPA proposed. Based on evaluation, market complaint coordinator shall decide to send back the record for more information from SME or shall complete the final quality assessment.
If any additional information is required from SME, Market complaint coordinator shall mention appropriate comment in activity summary to send back record.
If investigation performed and supporting documents provided by SME is adequate, Market complaint coordinator shall perform Final Quality Assessment.

6.9.1 Market Complaint Coordinator shall verify the details provided by investigator regarding complaint sample and photographs. Coordinator may provide additional details, if required for description of sample / photographs.

6.9.2 **Validity:** Based on the information available, initial assessment and outcome of investigation, market complaint coordinator shall select appropriate validity of the complaint as Genuine / Non-Genuine. As a general guidance,
If the complaint is non-genuine, coordinator shall summarize the assessment performed and final classification shall be Not Applicable as final risk assessment will not be required. Further CAPA plan, conclusion of investigation MCC response report details shall be appropriately provided. If validity is selected as Genuine, perform risk assessment and final classification as guided below.

6.9.3 **Nature of Complaint – Final:** Based on the investigation, if the nature of complaint needs to be changed, appropriate nature of complaint shall be selected.

6.9.4 **Final Action Comments:** Provide comments on actions taken during the course of market complaint initiation and investigation, with respect action completion status and their appropriateness / adequacy. Record if any additional action to be taken**.**

6.9.5 **Final Scope Assessment:** Market complaint coordinator shall summarize the scope of Market Complaint with the information gathered during course of investigation. The final

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scope of the market complaint shall cover all products, lines/equipment, personnel, etc. identified as a result of the investigation.
If the scope of the market complaint change and regulatory communication or action (Field Alert/Recall etc.) was initiated during the initial assessment, immediately notify to the Head of Quality. Any changes with respect to impact on the following areas shall be recorded along with justification.

- Regulatory Compliance
- Safety / Heath
- Documentation / Data
- Product Quality & Safety
- Validation
- Stability

Impact on any aspects other than those specified above, market complaint coordinator shall record details of other impact against 'Other Parameter'.

6.9.6 **Risk Assessment:** The Market complaint Coordinator shall perform a final classification in consideration with outcome of investigation findings and risk assessment shall be performed as per step no. 6.3.2.

Based on the Occurrence- Severity-Detectability values system will populate final classification (minor / major / critical).

6.9.7 **Assessment Summary and Final Market complaint Classification:** Requirement to hold complaint batch/(es) or impacted batch/(es) (if still within Wockhardt control) shall be assessed by Market Complaint Coordinator. Market complaint coordinator shall communicate such requirement to appropriate stakeholder. The Market complaint Coordinator shall summarize assessment performed, actions taken, communications made within this section and record justification in support of the classification. Any Additional comments regarding the market complaint can also be recorded under this field
Market complaint Coordinator shall select the final Market complaint Classification. If the Market complaint Coordinator overrides the system generated classification, a justification must be included in the Assessment Summary.

6.9.8 **PVG Communication Completed:** Coordinator shall verify whether PVG communication has been completed for the complaint categorized as ADR /ADE / LOE. Document related to communication shall be attached to PVG attachment.

6.9.9 **CAPA Plan Finalization:** The Market complaint Coordinator shall review the CAPA proposed or justification for no CAPA, provided by SME. Market complaint coordinator can overwrite the proposed CAPA plan.

6.9.10 **Conclusion of Investigation:** Market complaint coordinator shall conclude the investigation performed under this section. Following activities shall be carried out and documented, summarization of the investigation, finalization of primary and contributory root cause and sub-causes or justification for no root cause, Material disposition decision for the impacted product / batch.

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Note: Select 'Root Cause' where exact root cause is identified and select 'contributory root cause' where exact root cause is not identified.

6.9.11 **MCC Response Report:** Coordinator shall verify whether response report to the complainant has been sent and select appropriate option YES / NO. If response report has been sent date on which report has been sent shall be mentioned against field 'Report Sent Date' and relevant documents shall be attached as 'File Attachment MCC Report'. If response is not sent during the course of final QA assessment appropriate remark shall be included in comments section and confirm details of response report sending during Record Closure by MCC.

6.9.12 **Identification of Approver:** Market complaint Coordinator shall identify appropriate functions and individuals for review of the market complaint record. At a minimum the Head of the Department for the SME (Investigator) must be selected. In addition, market complaint coordinator may decide to identify head of cross functional team involved in the market complaint investigation. The Site Head must be identified for all market complaints which is having final QA classification as critical. Market complaint coordinator may decide to identify site head for market complaints classified other than critical.

6.9.13 Market complaint coordinator shall sign-off the record electronically, if record is to be submitted for further approval.

6.10 **SME Approval**: SME shall review the final quality assessment done by the market complaint coordinator and check the activity to be performed as part of action item or CAPA. If the assessment conducted is inappropriate or more information is required for any additional CAPA suggested by market complaint coordinator, SME shall provide adequate comment in activity summary and send the record back to 'Final Quality Assessment' stage. If the final assessment completed by market complaint coordinator is adequate, based on comments or assessment, SME shall create an action item and / or CAPA as child record in-line with proposal made. Respective operating procedure shall be followed to create child record. After successful submission of child records, SME shall sign-off the record electronically and approve the parent record.

6.11 **Head of Department for SME (Investigator)**: HOD of SME shall review the record and verify the contents of initiation, investigation and assessment. If additional information or additional action is required to simplify the process, HOD of SME shall provide appropriate comment in activity summary and send back the record to market complaint coordinator for appropriate modification. If the details provided by SME and market complaint coordinator are appropriate, HOD of SME shall electronically sign-off and process the record for approval by cross-functional department heads.

6.12 **HOD of Cross Functional Team (CFT):** All HOD of CFT identified by market complaint coordinator shall review the record and verify the contents of initiation, investigation and assessment. If additional information is required for better clarity on the action to be performed, HOD of CFT shall provide appropriate comment in activity summary and send back the record to market complaint coordinator for appropriate modification. If the details provided by initiator, SME and market complaint coordinator are appropriate, HOD of CFT shall electronically sign-off and process the record for closure review.

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6.13 **Closure Review**: Market complaint coordinator shall verify that relevant action item and / or CAPA are created in-line as proposed and acceptance from all HOD are provided. If more information is required from HOD, market complaint coordinator shall provide appropriate comment in activity summary and send record to HOD. If adequate information is available, market complaint coordinator shall electronically sign-off the record for further processing of record.

Note: If market complaint is classified as Minor, record will move to 'Pending action item submission' state. On successful submission of all action items, market complaint coordinator shall perform record closure.
If market complaint is classified as major / critical, record will move for Quality Head approval / Site Head approval respectively after successful closure review by market complaint coordinator.

6.14 **Site Head Approval**: Site head shall review the entire record and verify the same for its adequacy. If more detail is required, Site Head shall provide appropriate comment in the activity summary and send the record back to market complaint coordinator. If appropriate information is available, Site Head shall approve the record by signing-off electronically.

6.15 **Quality Head Approval**: Quality Head shall verify the record for its adequacy and appropriate attachments of supporting documents. If more information regarding the record is required, Quality Head shall comment appropriately in activity summary and send the record back to market complaint coordinator. If satisfactory details are provided and are acceptable, Quality Head shall electronically sign-off to approve the record.

6.16 **Response to Complainant:**

6.16.1 Quality Head / Market Complaint Coordinator shall send final response to complainant directly or through business partners.

6.16.2 Response shall be sent to complainant within 30 calendar days after receipt of the complaint. If the timelines are different as per Technical Agreements with Marketing Authorization holder or Contract Giver, same shall be followed.

6.16.3 For any queries received on the response / report, Quality Head is responsible to address them. If required, Quality Head shall propose for additional investigation and based on the outcome, a response shall be prepared and forwarded to complainant.

6.16.4 If there is no response from complainer for three follow ups then document these follow ups with evidence and close complaint. At later if information received then we can reopen complaint for further investigation.

6.17 **Record Closure by Market complaint Coordinator:** Market complaint coordinator shall verify the completeness, adequacy of the record, closure of required action items (if any) and acknowledgment from the complainant. If no acknowledgement is received from complainant within 15 calendar days after response to the complainant or business partner, the complaint shall be closed.

Note1: Adequate effort shall be made to reach out to the complainant for an acknowledgement of the complaint response.
Based on verification, market complaint coordinator shall provide the closure comments

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against field 'Closure Review Comments' and shall attach any supporting document, if any. On successful verification of the record, it shall be electronically signed and closed.

Note2: Market complaint can be closed if CAPA record is successfully submitted, but not closed due to extended time period for its completion date.

6.18 Creation of Extension:

6.18.1 Extension for market complaint can be created by all stages owners except for 'Initiation', 'Additional Approval' and 'Site Head Approval' stage owners.

6.18.2 Principle and business rule for creation of extension is defined in this section. System operating procedure for generation and approval of Extension is defined in **SOP No. WI-CQ-S0169.**

6.18.3 Extension process involves following steps.
Initiation
HOD review
Quality Head approval
Corporate Quality Head approval (in case of 2nd extension and above)

6.18.4 If a specific activity within Market Complaint management process i.e.: Impact / risk assessment, investigation, identified action completion or any other action is envisaged to take longer time than the Closure due date of the Market Complaint. Extension request shall be created and approved prior to or on the due date of Market Complaint.

6.18.5 For any extension request, appropriate justification shall be provided specifying which activity cannot or couldn't be completed within the scheduled closure due and the reason for not completing the activity. Justification shall also include impact of delay in completion of the particular activity/action, interim controls taken or proposed, line of action to complete outstanding activities within proposed due date.

6.18.6 If for any reason extension is not created and approved prior to or on the due date system will lock the market complaint record and cannot be worked upon unless an extension is initiated and approved.

6.18.7 HOD shall review the extension request raised by initiator and shall either approve, cancel the extension request. If HOD needs additional information on the justification provided, record shall be sent back to initiator with appropriate remarks in activity summary.

6.18.8 Quality Head and Corporate Quality (Corporate Quality approval applicable for 2nd extension onwards) shall review justification provided for extension and may decide to approve or reject extension request. If Quality Head or Corporate Quality need additional information on justification provided shall send back the record with appropriate remark in activity summary.

6.18.9 Extension approver shall verify the justification for creation of extension and impact of extension, if any.

Note: Extension of all paper based Market Complaint (prior to EQMS) system implementation and Extension of Market Complaint in case of Exigency shall be taken through **WICQS0008-A06**.

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6.19 Retention of Complaint Samples:

6.19.1 Complaint sample shall be stored as per product storage condition requirement till closure of investigation with appropriate labeling and control.

6.19.2 Complaint Sample shall be retained for at least one year after the expiry date of the drug product or one year after the date on which the complaint was received, whichever is longer.

6.19.3 Complaint sample shall be preserved to maintain integrity / intactness of complaint sample, suitably identified and securely handled and stored, to ensure that there is no possibility of a mix-up.

6.19.4 Destruction of complaint sample shall be done as per respective site procedure.

6.19.5 If the complaint samples are more in number then representative complaint sample can be kept and remaining samples can be destroyed after closure of investigation and photograph of these samples shall be kept along with complaint documents.

6.20 Re-opening of closed Market complaint:

6.20.1 The closed Market Complaint can be re-opened, due to following reasons, but are not limited to:

- Receipt of samples or other information which may trigger re-evaluation of the market complaint after closure of complaint.
- Any internal or external observation indicating gap within the market complaint process.
- Enhancement of the market complaint summary report for better clarity.

6.20.2 Quality Head is only authorized to re-open the record, if required. Quality head shall re-open the record and provide appropriate justification for re-opening against ‘Reason for Reopening’ field and attach the relevant document supporting the justification.

6.20.3 After reopening the record, Quality Head shall select appropriate stage i.e. “Opened” / “Initial QA Assessment” / “Extended Investigation” / “Final Quality Assessment” and proceed further by signing-off electronically.

6.21 Exigency Handling:

6.21.1 Whenever Enterprise Quality Management System (EQMS) is not available or malfunctioning, user shall adopt hard copy system. Whenever exigency is to be executed, it shall be numbered as E/MC/XX/YYYY-NNN
where E stands for Exigency,
MC stands for Market complaint,
XX stands for Facility Code or Division,
YYYY indicates current calendar year,
NNN indicates serial number assigned to market complaint in 3 digits.
QA shall log the exigency number in **WICQS0008-A08** This can be conducted when new market complaint is to be initiated or existing market complaint is to be processed. If new market complaint is initiated through exigency same shall be transcribed to EQMS whenever

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system is available. Reference of the exigency number shall be mentioned in the content, as well as same document shall be scanned and attached to the record as evidence. In cases where executed market complaint is to be processed further through exigency, print out of the executed record shall be taken and remaining stages shall be processed on the hard copy, mentioning the reference number of exigency at executed stages. For exigency market complaint form refer annexure **WICQS0008-A09**.

6.22 Timelines:

6.22.1 Acknowledging the complaint within 3 calendar days from the receipt.

6.22.2 Critical Complaint shall be notified to Head Quality within 1 calendar day via mail or suitable mean of communication.

6.22.3 In case of Critical complaints, initial report shall be sent in 7 calendar days, if the investigation is ongoing.

6.22.4 Investigation for all complaints shall be completed within 30 calendar days from the date of complaint receipt. All complaints shall be closed within 45 calendar days from the date of receipt.

6.23 Trending and Summary:

6.23.1 Market complaint Coordinator shall prepare summary and trending of market complaints on quarterly basis in every calendar year starting from January. Refer annexure **WICQS0008-A07** for trending and summary of market complaint.

6.23.2 Trending shall cover but not limited to total number of complaint received, category of market complaint, Nature of market complaint, classification of market complaint, root cause/ contributing cause/ sub-cause, No. of genuine, non-genuine complaints. Total No. of Complaints closed, No. of on time closure complaints (closed within 45 days), No. of overdue complaint which are not closed (45 days), Open (46 to 90 days), Open (91 days to 120 days), Open above 120 days and Re-opened complaints. Status of market complaint of all open and repeat market complaint shall be listed, and summarized with conclusion. Wherever required CAPA for repetitive market complaint shall be reviewed based on trend analysis to take additional CAPA measures.

Note: During trending for subsequent quarter, previous three quarters data also shall be used to ensure rolling data is considered. This summary and trending shall cover all those market complaints which are open in previous quarters.

6.23.3 Market Complaint trends shall be reported to management through Management Review-Corporate Quality Committee and Site Quality Committee as per procedure SOP: **WI-CQ-S0013.**

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7.0 ANNEXURES:

Annexure No.	Annexure Title	Usage Type
WICQS0008-A01	Market complaint process flow	For Reference
WICQS0008-A02	Different combination of occurrence-severity-detectability values for classification of market complaint	For Reference
WICQS0008-A03	Guidance for market complaint investigation	For Reference
WICQS0008-A04	Complaint / retention (or) reserve sample analysis request and report	As such
WICQS0008-A05	List of root cause and root cause sub-category	For Reference
WICQS0008-A06	Exigency form for extension of market complaint	As such
WICQS0008-A07	Trending and summary of market complaint	Computerized
WICQS0008-A08	Exigency market complaint log	As such
WICQS0008-A09	Exigency market complaint form	As such
WICQS0008-A10	Specimen Label for Complaint sample	For Reference

8.0 ABBREVIATIONS:

ADR : Adverse Drug Reaction
ADE : Adverse Drug Events
API : Active Pharmaceutical Ingredients
CAPA : Corrective and Preventive Action
CFR : Code of Federal Regulations
CFT : Cross Functional Team
cGMP : Current Good Manufacturing Practice
EQMS : Enterprise Quality Management System
EU : European Union
HOD : Head of the Department
ICH : International Council for Harmonization
LOE : Lack of Effect
MAH : Marketing Authorization Holder
MC : Market Complaint
MCC : Market Complaint Coordinator
MOH : Ministry of Health
PR : Project Record
PVG : Pharmacovigilance
QA : Quality Assurance
QMS : Quality Management System

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QP : Qualified Person
SME : Subject Matter Expert
SOP : Standard Operating Procedure
TPO : Third Party Organization

9.0 REFERENCES:

9.1 USFDA-21 CFR PART 211 -- Current Good Manufacturing Practice For Finished Pharmaceuticals, Subpart J--Records and Reports; 211.198

9.2 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Part 1, Chapter 8: Complaints, Quality Defects and Product Recalls

9.3 ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredient.

9.4 ANVISA GMP Guideline: Resolution - RDC No. 17, Dated April 16th, 2010, DOU (Brazilian Official Gazette) 04/19/10

9.5 WHO Guideline, TRS 908: Quality management in the drug industry: philosophy and essential elements.

9.6 HPRA: - Guide to Reporting and Initial Investigation of Quality Defects in Medicinal Products for Human and Veterinary Use, SUR-G0023-6 15 February 2019

9.7 Brazilian Health Surveillance Agency, Guide for Transport Qualification of Biological Products, Effective as of 04/12/2017, Guide No. 02/2017- Version 02

9.8 WHO Guideline, TRS 961 Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products.

9.9 SOP WI-CQ-S0001 “Procedure for Standard Operating Procedure”

9.10 SOP WI-CQ-S0011 “Corrective and Preventive Action (CAPA)”

9.11 SOP WI-CQ-S0012 “Quality Risk Management”

9.12 SOP WI-CQ-S0013 “Procedure for Quality Management Review and Notification to Management”

9.13 SOP WI-CQ-S0028 “Product Recall”

9.14 SOP WI-CQ-S0127 “Handling of market Complaint for Products Manufactured at Contract Manufacturing Sites”.

9.15 SOP WI-CQ-S0169 “Track wise system operation guide for Market Complaint”.

9.16 SOP WI-IT-S0014 “Handling of Operational Issues and Queries in Track wise”.

STANDARD OPERATING PROCEDURE

SOP TITLE	**MARKET COMPLAINT**		
FACILITY NAME	**WOCKHARDT India**	**DEPARTMENT**	**Corporate Quality**
SOP NO.	**WI-CQ-S0008**	**VERSION NO.**	**4.0, CURRENT**
EFFECTIVE DATE	**May 08, 2022**	**NEXT REVIEW DUE**	**May 07, 2025**

10.0 SUMMARY OF CHANGES:

Change Control Ref. No: CC/WI-CQ/2022-007 (PR # 83809)	
Description of Changes:	
1.	SOP is revised as per recommendation received from INVIMA audit, Instruction included under note in Point No. 6.6.1.1 as, "If required, the marketing authorization holder (MAH) of particular country (Wockhardt/Partner/Agent/CNF) shall extend the investigation of the complaint up to stockiest or distributor level to ensure, there no similar nature of complaint for same lots".