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Handling of Product Quality Complaints

Category: Quality Assurance

Standard Operating Procedure (SOP)

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Department: Quality Assurance

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1.0 PURPOSE

This procedure establishes a standardized method for receiving, documenting, evaluating, investigating, resolving, and tracking product quality complaints at NovaThera Pharmaceuticals to ensure compliance with GMP and regulatory requirements and to facilitate continuous improvement in pharmaceutical manufacturing processes.

2.0 SCOPE

This SOP applies to all departments and personnel at NovaThera Pharmaceuticals Pvt. Ltd. involved in the handling of product quality complaints related to manufactured pharmaceutical products, including raw materials, in-process materials, finished goods, packaging components, and any other materials that may affect product quality. This SOP is applicable to all batches and products manufactured at the facility. It excludes complaints related to employee grievances, marketing materials, or non-product related services.

3.0 RESPONSIBILITY

QC Inspector:

- Receives and logs product quality complaints.
- Performs initial assessment of the complaint and gathers necessary information.
- Submits initial complaint information to the QA Manager.
- Collects and submits retain samples for investigation, as requested by QA Manager.
- Assists in the investigation process, as required.
- Documents all activities performed related to the complaint.

Production Supervisor:

- Provides information regarding the manufacturing process of the product associated with the complaint.
- Assists in identifying potential root causes of the complaint.
- Implements corrective and preventative actions (CAPA) assigned by the QA Manager.
- Ensures adherence to established manufacturing procedures.
- Reports any deviations from standard procedures to the QA Manager.

QA Manager:

- Reviews and evaluates product quality complaints.
- Initiates and oversees investigations into the root cause of complaints.
- Assigns responsibilities to relevant departments for investigation and resolution.
- Determines the need for product recall or market withdrawal, in consultation with the Head of QA.
- Prepares investigation reports and proposes corrective and preventative actions (CAPA).
- Tracks the progress of complaint investigations and CAPA implementation.
- Communicates with regulatory authorities, as required, in consultation with the Head of QA.
- Ensures timely closure of complaint investigations and documentation.

Head of QA:

- Provides oversight of the product quality complaint handling process.
- Reviews and approves investigation reports and CAPA plans.
- Makes the final decision on the disposition of affected products.
- Communicates with senior management regarding significant quality issues.
- Ensures compliance with GMP regulations and company policies.
- Acts as the final authority on all product quality complaint related matters.
- Approves product recalls or market withdrawals in consultation with senior management.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses

- Laboratory coat
- Disposable gloves
- Face mask (as required)

Equipment:

- Calibrated pH meter (PHM-01)
- Analytical balance (ALB-02)
- Microscope (MIC-01)
- Environmental monitoring equipment (ENV-01)
- Computer with internet access
- Temperature and humidity monitoring system (THM-01)

Documentation:

- Product Quality Complaint Form (QA-F-011-01)
- Complaint Logbook (QA-R-011-01)
- Investigation Report Template (QA-F-011-02)
- CAPA Form (QA-F-011-03)
- Deviation Report Form (QA-F-005-01)
- Batch Manufacturing Record (BMR) for the product in question
- Retain Sample Logbook (QA-R-008-01)

5.0 PROCEDURE

5.1 RECEIVING AND LOGGING COMPLAINTS

5.1.1 Any product quality complaint received via phone, email, written correspondence, or any other means shall be immediately reported to the QC Inspector.

5.1.2 The QC Inspector shall record the complaint details on the Product Quality Complaint Form (QA-F-011-01), including the date and time of receipt, complainant's name and contact information, product name, batch number, date of manufacture, and a detailed description of the complaint.

5.1.3 The QC Inspector shall assign a unique complaint number to each complaint, following the format: NT-COMP-YYYY-NNN (where YYYY is the year and NNN is a sequential number).

5.1.4 The QC Inspector shall enter the complaint information into the Complaint Logbook (QA-R-011-01), including the complaint number, product name, batch number, complainant information, a brief summary of the complaint, and the date the complaint was logged.

5.1.5 The QC Inspector shall acknowledge receipt of the complaint to the complainant within 24 hours, if contact information is available.

5.1.6 The QC Inspector shall immediately notify the QA Manager of the received complaint and provide a copy of the completed Product Quality Complaint Form (QA-F-011-01).

5.2 INITIAL ASSESSMENT

5.2.1 The QA Manager shall review the Product Quality Complaint Form (QA-F-011-01) and assess the severity and potential impact of the complaint on product quality, patient safety, and regulatory compliance.

5.2.2 The QA Manager shall determine if the complaint is a critical complaint, a major complaint, or a minor complaint based on the following criteria:

- Critical Complaint: Complaint involving a serious risk to patient safety or product efficacy. Examples include misidentification of product, presence of foreign matter, or significant degradation.
- Major Complaint: Complaint involving a potential risk to patient safety or product efficacy, or a significant deviation from product specifications. Examples include incorrect labeling, sub-potency, or significant discoloration.
- Minor Complaint: Complaint involving a minor deviation from product specifications with little or no impact on patient safety or product efficacy. Examples include minor cosmetic defects or slight variations in fill volume.

5.2.3 The QA Manager shall document the severity classification on the Product Quality Complaint Form (QA-F-011-01).

5.2.4 If the complaint is classified as critical, the QA Manager shall immediately notify the Head of QA and initiate an immediate investigation.

5.2.5 The QA Manager shall determine the need for collecting retain samples of the affected product for further investigation. If retain samples are required, the QA Manager shall instruct the QC Inspector to retrieve the samples from the retain sample storage area.

5.2.6 The QC Inspector shall retrieve the retain samples, record the sample details in the Retain Sample Logbook (QA-R-008-01), and submit the samples to the laboratory for testing, as requested by the QA Manager.

5.3 INVESTIGATION

5.3.1 The QA Manager shall initiate an investigation using the Investigation Report Template (QA-F-011-02) to determine the root cause of the complaint.

5.3.2 The QA Manager shall assign responsibilities to relevant departments, such as Production, QC, and Engineering, to participate in the investigation.

5.3.3 The QA Manager shall review the Batch Manufacturing Record (BMR) for the affected batch, including raw material certificates of analysis, in-process control data, and finished product testing results.

5.3.4 The QA Manager shall review any relevant deviation reports (QA-F-005-01) or change control records related to the affected product or process.

5.3.5 The Production Supervisor shall provide information regarding the manufacturing process, including equipment used (e.g., BLN-04, TCP-01, SFT-02), process parameters, and any deviations from standard procedures.

5.3.6 The QC Inspector shall perform laboratory testing on the retain samples, including but not limited to visual inspection, pH testing using PHM-01, assay testing using ALB-02, and microscopic examination using MIC-01.

5.3.7 The QA Manager shall conduct interviews with relevant personnel to gather additional information and insights regarding the complaint.

5.3.8 The QA Manager shall document all findings and conclusions in the Investigation Report Template (QA-F-011-02).

5.3.9 The QA Manager shall identify the root cause of the complaint based on the investigation findings. If the root cause cannot be determined, the investigation shall be extended, and further investigation steps shall be taken.

5.3.10 The QA Manager shall propose corrective and preventative actions (CAPA) to address the root cause of the complaint and prevent recurrence.

5.3.11 The proposed CAPA shall be documented on the CAPA Form (QA-F-011-03), including the responsible department, the target completion date, and the expected outcome.

5.4 CORRECTIVE AND PREVENTATIVE ACTIONS (CAPA)

5.4.1 The QA Manager shall review the proposed CAPA with the Head of QA and obtain approval.

5.4.2 The QA Manager shall assign responsibility for implementing the CAPA to the relevant department(s).

5.4.3 The Production Supervisor shall implement the CAPA as assigned, ensuring adherence to established procedures and timelines. This may

include revising SOPs, retraining personnel, modifying equipment, or implementing process controls.

5.4.4 The QC Inspector shall verify the effectiveness of the CAPA through follow-up testing and monitoring.

5.4.5 The QA Manager shall track the progress of CAPA implementation and monitor the completion of assigned tasks.

5.4.6 The QA Manager shall document the completion of the CAPA on the CAPA Form (QA-F-011-03), including the date of completion, the results of verification testing, and any relevant observations.

5.4.7 The QA Manager shall evaluate the effectiveness of the CAPA in preventing recurrence of the complaint. If the CAPA is not effective, the investigation shall be reopened, and further corrective actions shall be taken.

5.4.8 The QA Manager shall close the CAPA loop by documenting the final evaluation and approval on the CAPA Form (QA-F-011-03).

5.5 PRODUCT DISPOSITION

5.5.1 Based on the severity of the complaint and the results of the investigation, the QA Manager, in consultation with the Head of QA, shall determine the disposition of the affected product.

5.5.2 The possible dispositions include:

- Acceptable: The product meets all quality standards and is suitable for release.
- Rework: The product can be reprocessed or retested to meet quality standards.
- Reject: The product does not meet quality standards and must be discarded or destroyed.
- Recall: The product has been distributed to the market and must be recalled due to a significant quality defect.

5.5.3 The QA Manager shall document the product disposition decision in the Investigation Report Template (QA-F-011-02), including the rationale for the decision.

5.5.4 If a product recall is necessary, the QA Manager shall initiate the product recall procedure according to SOP-QA-012 (Product Recall Procedure), in consultation with the Head of QA and senior management.

5.6 TRENDING AND ANALYSIS

5.6.1 The QA Manager shall periodically review the Complaint Logbook (QA-R-011-01) to identify trends in product quality complaints.

5.6.2 The QA Manager shall analyze the complaint data to identify recurring issues, common root causes, and areas for improvement.

5.6.3 The QA Manager shall prepare a summary report of the complaint trends and analysis and present the report to senior management for review and action.

5.6.4 The trending and analysis data shall be used to identify opportunities for continuous improvement in pharmaceutical manufacturing processes.

6.0 POST-ACTIVITY ACTIVITIES

6.0.1 The QA Manager shall ensure that all records related to the product quality complaint are properly filed and archived.

6.0.2 The QA Manager shall ensure that the Complaint Logbook (QA-R-011-01) is updated with the final disposition of the complaint and the CAPA status.

6.0.3 The QA Manager shall periodically review the effectiveness of this SOP and make revisions as necessary.

6.0.4 The Head of QA shall review and approve all revisions to this SOP.

7.0 SAFETY PRECAUTIONS

7.0.1 Always wear appropriate PPE, including safety glasses, laboratory coat, disposable gloves, and face mask (as required), when handling product samples or conducting investigations.

7.0.2 Follow all laboratory safety procedures when performing testing.

7.0.3 Handle chemicals and reagents in accordance with their respective Safety Data Sheets (SDS).

7.0.4 Report any accidents or incidents to the appropriate personnel immediately.

7.0.5 Be aware of potential hazards associated with the product being investigated and take appropriate precautions.

7.0.6 Dispose of waste materials in accordance with established waste management procedures.

7.0.7 Ensure the work area is clean and organized to prevent accidents.

8.0 APPROVALS

Prepared By: QA Specialist

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
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