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# Handling of Product Recalls

**Category:** Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Assurance

**Title: Handling of Product Recalls**

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## 1.0 PURPOSE

This procedure defines the steps for effectively managing and executing product recalls within NovaThera Pharmaceuticals' pharmaceutical manufacturing operations. This SOP ensures prompt and appropriate action to protect public health and maintain compliance with all applicable regulatory requirements, including GMP and FDA/ICH guidelines. It outlines the responsibilities, documentation, and activities required for identifying, assessing, initiating, implementing, and documenting product recalls.

## 2.0 SCOPE

This Standard Operating Procedure (SOP) applies to all pharmaceutical products manufactured, packaged, labeled, and distributed by NovaThera Pharmaceuticals Pvt. Ltd. It covers all product recalls, regardless of the reason, including but not limited to defects, mislabeling, contamination, stability issues, or regulatory concerns. This SOP applies to all departments involved in the recall process, including Quality Assurance, Production, Regulatory Affairs, Distribution, and Sales. It includes all batches of any product manufactured at NovaThera Pharmaceutical facilities. This procedure does not cover market withdrawals or returns that are not due to product defects or regulatory concerns.

## 3.0 RESPONSIBILITY

**QC Inspector:**

- Supports the QA Manager in investigating product defects or complaints that may lead to a recall.
- Collects and analyzes samples of the affected product for testing.
- Documents all inspection and testing activities according to GMP.
- Communicates findings to the QA Manager in a timely manner.

**Production Supervisor:**

- Provides information regarding the manufacturing process, batch records, and any deviations that may have occurred during the production of the affected product.
- Assists in identifying potentially affected batches based on manufacturing records.
- Implements corrective actions in the production process to prevent recurrence of the issue that led to the recall.
- Ensures proper segregation and quarantine of affected product.

**QA Manager:**

- Evaluates all potential recall situations based on product defects, complaints, and regulatory requirements.
- Initiates and manages the product recall process, including the preparation of recall documentation.
- Coordinates with all relevant departments to ensure timely and effective implementation of the recall.
- Oversees the investigation of the root cause of the recall.
- Communicates with regulatory authorities regarding the recall, as required.
- Reviews and approves the recall strategy and effectiveness checks.
- Ensures that all recall activities are documented appropriately.

**Head of QA:**

- Provides final approval for all product recall decisions and strategies.
- Acts as the primary contact with regulatory authorities regarding product recalls.
- Oversees the overall effectiveness of the recall process.
- Ensures that the recall process is aligned with GMP and regulatory requirements.
- Has overall responsibility for the review and approval of the final recall report.
- Approves changes to the recall SOP and related procedures.

## 4.0 MATERIALS & EQUIPMENT

**PPE:**

- Safety glasses
- Gloves (nitrile or appropriate material for handling recalled product)
- Lab coats
- Face masks (if required based on the nature of the recall)

**Equipment:**

- Computer with internet access for communication with regulatory agencies and customers.
- Telephone for communication with customers and distributors.
- Calibrated weighing scales (ACC-08) for reconciliation of returned product.
- Sample collection tools (SPTL-01)
- Temperature and humidity monitoring devices (THM-03)
- Label printer (LBL-01) for printing quarantine labels.

**Documentation:**

- Product Recall Initiation Form (QA-FRM-012-01)
- Product Recall Assessment Form (QA-FRM-012-02)
- Product Recall Communication Plan (QA-FRM-012-03)
- Product Recall Distribution List (QA-FRM-012-04)
- Product Recall Acknowledgement Form (QA-FRM-012-05)
- Product Reconciliation Form (QA-FRM-012-06)
- Product Destruction Record (QA-FRM-012-07)
- Deviation Report Form (QA-FRM-008-01)
- Corrective and Preventive Action (CAPA) Form (QA-FRM-009-01)
- Complaint Log (QA-REC-005-01)
- Batch Manufacturing Record (BMR) of the affected product.
- Distribution records of the affected product.

## 5.0 PROCEDURE

### 5.1 Identification and Assessment of a Potential Recall Situation

#### 5.1.1 Any employee who identifies a potential product defect, receives a complaint, or becomes aware of a regulatory concern that could lead to a recall must immediately notify the QA Manager.

**5.1.2 The QC Inspector will document the potential issue in the Complaint Log (QA-REC-005-01) and gather all relevant information, including batch numbers, distribution records, and any available samples.**

**5.1.3 The QA Manager will initiate the Product Recall Assessment Form (QA-FRM-012-02) to document the initial assessment of the situation.**

**5.1.4 The QA Manager will evaluate the potential risk to public health, the severity of the defect, and the extent of distribution of the affected product. This assessment will include a review of the Batch Manufacturing Record (BMR), any associated deviation reports, and relevant stability data.**

**5.1.5 The QC Inspector will collect and analyze samples of the affected product using appropriate testing methods according to approved specifications.**

**5.1.6 If the QA Manager determines that a recall is necessary, based on the assessment and test results, the QA Manager will notify the Head of QA immediately.**

**5.2 Initiation of the Recall Process**

**5.2.1 The Head of QA will review the assessment and make the final decision regarding the initiation of a product recall. The decision will be documented on the Product Recall Initiation Form (QA-FRM-012-01).**

**5.2.2 If a recall is initiated, the QA Manager will prepare a detailed Product Recall Communication Plan (QA-FRM-012-03), including the scope of the recall, the reason for the recall, the affected product and batch numbers, and instructions for returning the product.**

**5.2.3 The QA Manager will establish a Product Recall Distribution List (QA-FRM-012-04) containing contact information for all customers,**

**distributors, and regulatory agencies who need to be notified of the recall.**

**5.2.4 The QA Manager will prepare a draft recall notice for approval by the Head of QA. The notice will include clear and concise information about the recall, the affected product, the potential risks, and instructions for returning the product.**

**5.3 Implementation of the Recall**

**5.3.1 The QA Manager, upon approval from Head of QA, will notify all customers, distributors, and regulatory agencies according to the Product Recall Communication Plan (QA-FRM-012-03) and Distribution List (QA-FRM-012-04). The notification will be documented, including the date, time, and method of communication.**

**5.3.2 Customers and distributors will be instructed to immediately cease distribution of the affected product and quarantine all remaining inventory.**

**5.3.3 Customers and distributors will be provided with a Product Recall Acknowledgement Form (QA-FRM-012-05) to confirm receipt of the recall notice and their compliance with the recall instructions.**

**5.3.4 The Production Supervisor will ensure that all affected product within NovaThera Pharmaceuticals' facilities is immediately quarantined and labeled appropriately with quarantine labels generated using LBL-01.**

**5.3.5 The QA Manager will track the return of the recalled product using the Product Reconciliation Form (QA-FRM-012-06). This form will document the quantity of product distributed, the quantity returned, and the quantity outstanding.**

**5.3.6 The QA Manager will maintain accurate records of all recall-related communications, including emails, phone calls, and written**

**correspondence.**

**5.3.7 The QC Inspector will inspect and verify the returned product to confirm that it matches the affected batch numbers and is consistent with the reported defect.**

**5.4 Reconciliation and Disposal of Recalled Product**

**5.4.1 The QA Manager will reconcile the returned product against the distribution records to determine the effectiveness of the recall.**

**5.4.2 The QA Manager will prepare a final reconciliation report summarizing the results of the recall, including the quantity of product distributed, the quantity returned, the percentage of product recovered, and any outstanding inventory.**

**5.4.3 The Head of QA will review and approve the reconciliation report.**

**5.4.4 The QA Manager will determine the appropriate method of disposal for the recalled product based on the nature of the defect and regulatory requirements.**

**5.4.5 The QA Manager will document the disposal process in the Product Destruction Record (QA-FRM-012-07), including the date, method of disposal, and the quantity of product destroyed.**

**5.4.6 The disposal of the recalled product will be witnessed by at least two authorized personnel, including the QA Manager or designee and a representative from Production.**

**5.4.7 The QC Inspector will collect samples of the disposed product (if possible) for retention as part of the recall documentation.**

**5.5 Investigation and Corrective Action**

**5.5.1 The QA Manager will initiate an investigation to determine the root cause of the product defect that led to the recall.**

**5.5.2 The investigation will involve a review of the Batch Manufacturing Record (BMR), raw material records, equipment maintenance records, and any relevant deviations or complaints.**

**5.5.3 The Production Supervisor will provide input and assistance in the investigation, focusing on potential manufacturing-related causes.**

**5.5.4 The QA Manager will document the investigation findings in a Deviation Report Form (QA-FRM-008-01).**

**5.5.5 The QA Manager will develop a Corrective and Preventive Action (CAPA) plan (QA-FRM-009-01) to address the root cause of the defect and prevent recurrence.**

**5.5.6 The CAPA plan will include specific actions, timelines, and responsible parties.**

**5.5.7 The Head of QA will review and approve the CAPA plan.**

**5.5.8 The QA Manager will monitor the implementation of the CAPA plan and verify its effectiveness.**

**5.5.9 The QA Manager will document the results of the CAPA implementation in the CAPA form and close out the CAPA.**

**5.6 Recall Closure**

**5.6.1 Once the recall is complete, all product has been reconciled and disposed of, the root cause investigation is complete, and the CAPA plan has been implemented, the QA Manager will prepare a final recall report.**

**5.6.2 The final recall report will summarize all aspects of the recall, including the reason for the recall, the scope of the recall, the effectiveness of the recall, the root cause investigation findings, and the corrective actions taken.**

**5.6.3 The Head of QA will review and approve the final recall report.**

**5.6.4 The QA Manager will archive all recall-related documentation in accordance with NovaThera Pharmaceuticals' record retention policy.**

**5.6.5 The QA Manager will notify regulatory agencies of the completion of the recall, as required.**

## 6.0 POST-RECALL ACTIVITIES

6.1 The Head of QA will schedule a meeting with key personnel from Quality Assurance, Production, Regulatory Affairs, and Distribution to review the recall process and identify areas for improvement.

6.2 The QA Manager will update the product recall SOP (SOP-QA-012) as necessary to incorporate lessons learned from the recall.

6.3 The QA Manager will conduct training for all relevant personnel on the revised SOP.

6.4 The QA Manager will monitor the effectiveness of the CAPA plan to ensure that the defect does not recur.

6.5 The QA Manager will review the product stability data for the affected product to assess any potential long-term effects.

## 7.0 SAFETY PRECAUTIONS

7.1 Personnel involved in the handling of recalled product must wear appropriate PPE, including safety glasses, gloves, lab coats, and face masks, as required by the nature of the recalled product and the potential hazards.

7.2 Recalled product must be handled in a designated area to prevent cross-contamination of other products.

7.3 Spills or leaks of recalled product must be cleaned up immediately according to NovaThera Pharmaceuticals' spill control procedures.

7.4 Personnel must be trained on the hazards associated with the recalled product and the appropriate safety precautions.

7.5 If the recalled product contains hazardous materials, the disposal process must comply with all applicable environmental regulations.

7.6 Ensure proper ventilation when handling recalled products that may release dust or fumes.

7.7 Material Safety Data Sheets (MSDS) for all recalled products must be readily available.

## 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: | _____ | _____ | _____ |
| Reviewed by (QA): | _____ | _____ | _____ |
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