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Deviation Management and Reporting

Category: Quality Assurance

Standard Operating Procedure (SOP)

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Department: Quality Assurance

Title: Deviation Management and Reporting

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1.0 PURPOSE

This procedure defines the standardized process for the identification, documentation, evaluation, investigation, resolution, and reporting of deviations from established procedures, specifications, and GMP requirements during pharmaceutical manufacturing at NovaThera Pharmaceuticals. This ensures that all deviations are handled in a timely and effective manner to maintain product quality, patient safety, and regulatory compliance.

2.0 SCOPE

This SOP applies to all departments and personnel at NovaThera Pharmaceuticals involved in the manufacturing, testing, packaging, storage, and distribution of pharmaceutical products. It covers all deviations from approved standard operating procedures (SOPs), master production records (MPRs), specifications, regulatory guidelines, and other established quality standards. This SOP is applicable to all products and batches manufactured at NovaThera Pharmaceuticals Pvt. Ltd.

3.0 RESPONSIBILITY

QC Inspector:

- Identifies and documents deviations observed during routine inspections, testing, or sampling.
- Immediately reports deviations to the Production Supervisor and QA Manager.
- Assists in the investigation of deviations, as required.
- Verifies corrective and preventive actions (CAPA) effectiveness.

Production Supervisor:

- Ensures that all personnel are trained on this SOP and adhere to its requirements.
- Immediately reports deviations to the QA Manager.
- Initiates a preliminary investigation of deviations occurring within the production area.
- Implements immediate corrective actions to contain the deviation and prevent further occurrences.
- Provides input into the deviation investigation and CAPA plan.

QA Manager:

- Oversees the deviation management process.
- Reviews and approves deviation reports.
- Assigns responsibility for conducting thorough investigations.
- Evaluates the impact of deviations on product quality, patient safety, and regulatory compliance.
- Develops and implements CAPA plans to address the root cause of deviations.
- Tracks the progress of deviation investigations and CAPA implementation.
- Ensures that deviation reports are complete, accurate, and submitted in a timely manner.

Head of QA:

- Provides final review and approval of deviation reports, investigation findings, and CAPA plans.
- Ensures that the deviation management system is effective and compliant with regulatory requirements.
- Monitors deviation trends and identifies areas for improvement in manufacturing processes and quality systems.
- Periodically audits the deviation management system to ensure compliance.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or latex, as appropriate)
- Lab coats
- Shoe covers

Equipment:

- Calibrated thermometers (TMP-01, TMP-02)

- Calibrated pH meters (PHM-01, PHM-02)
- Balances (BAL-01, BAL-02)
- Relevant manufacturing equipment (BLN-04, TCP-01, SFT-02)
- Computers with network access
- Printers

Documentation:

- Deviation Report Form (NT-QA-FRM-005)
- Investigation Report Form (NT-QA-FRM-006)
- CAPA Plan Form (NT-QA-FRM-007)
- Batch Manufacturing Record (BMR)
- Standard Operating Procedures (SOPs)
- Equipment logbooks

5.0 PROCEDURE

5.1 Deviation Identification and Reporting

5.1.1 Any employee who observes a deviation from established procedures, specifications, or GMP requirements must immediately notify their supervisor.

5.1.2 The observer (QC Inspector, Production Supervisor, or other relevant personnel) must document the deviation on the Deviation Report Form (NT-QA-FRM-005) as soon as possible, but no later than 24 hours after the deviation is identified. The Deviation Report Form must include the following information:

- Date and time of the deviation
- Location of the deviation
- Description of the deviation, including the specific procedure, specification, or GMP requirement that was not met
- Product name and batch number (if applicable)
- Equipment involved (if applicable)
- Potential impact of the deviation

- Name and signature of the person reporting the deviation

5.1.3 The Production Supervisor must review the Deviation Report Form and immediately notify the QA Manager.

5.1.4 The QA Manager assigns a unique deviation number to the Deviation Report Form and records the deviation in the Deviation Log.

5.2 Preliminary Investigation

5.2.1 The Production Supervisor, in conjunction with the QA Manager, initiates a preliminary investigation to gather information about the deviation.

5.2.2 The preliminary investigation should include:

- Interviewing personnel involved in the deviation
- Reviewing relevant documentation (BMR, SOPs, equipment logbooks)
- Examining the affected product or material
- Assessing the potential impact of the deviation on product quality, patient safety, and regulatory compliance

5.2.3 The Production Supervisor documents the findings of the preliminary investigation on the Investigation Report Form (NT-QA-FRM-006).

5.2.4 The Production Supervisor and QA Manager determine if immediate corrective action is required to contain the deviation and prevent further occurrences. If immediate corrective action is taken, it must be documented on the Deviation Report Form and the Investigation Report Form.

5.3 Deviation Assessment and Impact Evaluation

5.3.1 The QA Manager reviews the Deviation Report Form and the Investigation Report Form to assess the severity of the deviation and its potential impact.

5.3.2 The QA Manager determines the scope of the investigation based on the potential impact of the deviation.

5.3.3 The QA Manager consults with relevant subject matter experts (e.g., microbiologist, chemist, engineer) to evaluate the technical aspects of the deviation.

5.3.4 The QA Manager documents the assessment and impact evaluation on the Investigation Report Form. The assessment includes:

- Classification of the deviation (e.g., critical, major, minor)
- Potential impact on product quality, patient safety, and regulatory compliance
- Justification for the classification and impact evaluation

5.4 Root Cause Investigation

5.4.1 Based on the assessment and impact evaluation, the QA Manager assigns responsibility for conducting a thorough root cause investigation. The investigation team should include personnel with the necessary expertise to identify the root cause of the deviation.

5.4.2 The investigation team uses appropriate root cause analysis tools (e.g., 5 Whys, Fishbone diagram) to identify the underlying cause(s) of the deviation.

5.4.3 The investigation team gathers data and evidence to support the identified root cause(s).

5.4.4 The investigation team documents the root cause investigation process and findings on the Investigation Report Form. The documentation includes:

- Description of the root cause analysis methodology used
- Data and evidence supporting the identified root cause(s)

- Conclusions of the investigation

5.5 Corrective and Preventive Action (CAPA) Plan

5.5.1 Based on the root cause investigation, the QA Manager, in collaboration with relevant departments, develops a CAPA plan to address the root cause of the deviation and prevent future occurrences.

5.5.2 The CAPA plan should include:

- Specific corrective actions to address the immediate problem
- Specific preventive actions to prevent recurrence of the deviation
- Clear assignment of responsibility for implementing each action
- Target completion dates for each action
- Metrics to measure the effectiveness of the CAPA plan

5.5.3 The CAPA plan is documented on the CAPA Plan Form (NT-QA-FRM-007).

5.5.4 The QA Manager reviews and approves the CAPA plan.

5.6 CAPA Implementation and Monitoring

5.6.1 The responsible personnel implement the CAPA plan according to the defined timelines.

5.6.2 The QA Manager monitors the progress of CAPA implementation.

5.6.3 The QA Manager documents the status of each CAPA action on the CAPA Plan Form.

5.6.4 Any delays or deviations from the CAPA plan must be documented and justified.

5.7 CAPA Effectiveness Verification

5.7.1 After the CAPA plan has been implemented, the QA Manager verifies the effectiveness of the CAPA actions.

5.7.2 The effectiveness verification should include:

- Reviewing data and metrics to assess the impact of the CAPA actions
- Conducting follow-up inspections or audits to verify that the deviation has been resolved
- Interviewing personnel to assess their understanding of the CAPA actions and their ability to prevent future occurrences

5.7.3 The QC Inspector may be involved in the verification process through additional testing or sampling.

5.7.4 The QA Manager documents the effectiveness verification process and findings on the CAPA Plan Form.

5.7.5 If the CAPA actions are not effective, the QA Manager revises the CAPA plan and repeats the implementation and verification steps.

5.8 Deviation Report Closure

5.8.1 Once the CAPA plan has been effectively implemented and verified, the QA Manager closes the deviation report.

5.8.2 The QA Manager ensures that all required documentation is complete and accurate.

5.8.3 The Head of QA reviews and approves the closure of the deviation report.

5.8.4 The closed deviation report is filed in the Deviation File.

6.0 POST-ACTIVITY ACTIVITIES

- 6.1 The QA Manager analyzes deviation trends on a quarterly basis to identify potential areas for improvement in manufacturing processes and quality systems.
- 6.2 The Head of QA presents the deviation trend analysis to senior management.
- 6.3 The QA Manager updates the Deviation Log with the closure date and status.
- 6.4 All deviation reports, investigation reports, and CAPA plans are retained in accordance with the company's record retention policy.
- 6.5 The training department updates training records for personnel involved in deviations as needed to ensure continued compliance.

7.0 SAFETY PRECAUTIONS

- 7.1 Always wear appropriate PPE (safety glasses, gloves, lab coats, shoe covers) when handling pharmaceutical materials and equipment.
- 7.2 Follow all safety procedures outlined in the relevant SOPs for handling specific materials and equipment.
- 7.3 Report any unsafe conditions or practices to the Production Supervisor immediately.
- 7.4 In case of accidental exposure to hazardous materials, follow the company's emergency response procedures.
- 7.5 Ensure proper disposal of waste materials in accordance with environmental regulations and company procedures.
- 7.6 When using equipment (BLN-04, TCP-01, SFT-02), ensure it is properly grounded and that all safety guards are in place. If any equipment malfunctions, immediately cease use and report it to the engineering department.

8.0 APPROVALS

Prepared By: QA Associate

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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Prepared by:	_____	_____	_____
Reviewed by (QA):	_____	_____	_____
Approved by (Head QA):	_____	_____	_____

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