Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-QA-013
Title:	Batch Record Review and Final Batch Release	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Batch Record Review and Final Batch Release

Category: Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Assurance

Title: Batch Record Review and Final Batch Release

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1.0 PURPOSE

This procedure establishes the standard for the review of completed batch records for pharmaceutical manufacturing at NovaThera Pharmaceuticals Pvt. Ltd. to ensure compliance with Good Manufacturing Practices (GMP), adherence to approved standard operating procedures, and verification that the batch meets all pre-determined specifications prior to final batch release.

2.0 SCOPE

This SOP applies to all completed batch records generated during the manufacturing of all pharmaceutical products manufactured at NovaThera Pharmaceuticals Pvt. Ltd. in Pune, India. This includes, but is not limited to, raw materials, in-process materials, and finished goods batch records. This SOP excludes the creation or modification of batch records; it is solely focused on the review and release process.

3.0 RESPONSIBILITY

QC Inspector:

- Performs initial review of the batch record for completeness, accuracy, and compliance with GMP.

- Verifies all calculations and data entries within the batch record.
- Identifies and documents any discrepancies, deviations, or errors noted during the review.
- Escalates any unresolved issues or discrepancies to the QA Manager.

Production Supervisor:

- Ensures that all required documentation is completed accurately and contemporaneously during the manufacturing process.
- Investigates and provides explanations for any deviations or discrepancies noted during the batch record review process.
- Implements corrective and preventive actions (CAPA) as required to address identified issues.

QA Manager:

- Oversees the batch record review and release process.
- Provides guidance and support to the QC Inspector during the review process.
- Evaluates the impact of any deviations or discrepancies on product quality and safety.
- Approves or rejects the batch based on the review findings and compliance with GMP regulations.
- Initiates and manages investigations related to deviations or discrepancies.

Head of QA:

- Provides final approval for the batch record review and release process.
- Ensures that the batch record review and release process is in compliance with all applicable regulations and company policies.
- Oversees the implementation of corrective and preventive actions (CAPA) to address systemic issues.
- Serves as the final decision-making authority in cases of unresolved discrepancies or disputes.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Laboratory coat
- Gloves

Equipment:

- Computer with access to the document management system
- Calibrated balance (LAB-001) for verification of yield calculations
- Calibrated thermometer (TMP-005) for environmental monitoring verification (if applicable)

Documentation:

- Approved Batch Record Template for the specific product

- Relevant Standard Operating Procedures (SOPs)
- Deviation/Incident Report Form (QMS-001)
- CAPA Form (QMS-002)
- Material Safety Data Sheets (MSDS) for raw materials
- Certificate of Analysis (COA) for raw materials and finished goods
- Equipment calibration records
- Training records for personnel involved in the manufacturing process
- Cleaning and sanitization logs

5.0 PROCEDURE

5.1 Batch Record Receipt and Initial Verification

5.1.1 Production Supervisor submits the completed batch record to the Quality Assurance department.

5.1.2 QC Inspector receives the batch record and logs it into the batch record tracking system. The log must contain date of receipt, batch number, product name, and the Production Supervisor who submitted the batch record.

5.1.3 QC Inspector verifies that all required sections of the batch record are present and complete.

5.1.4 QC Inspector verifies that all signatures and dates are present and legible. Any missing signatures or illegible entries must be immediately brought to the attention of the Production Supervisor for correction.

5.1.5 QC Inspector verifies that the batch number on the batch record matches the batch number on all associated documentation, including raw material COAs, in-process testing results, and equipment logs.

5.1.6 QC Inspector checks for any obvious errors or discrepancies in the batch record, such as missing data, incorrect calculations, or deviations from approved procedures.

5.2 Raw Material Verification

5.2.1 QC Inspector verifies that all raw materials used in the batch are approved for use and have valid Certificates of Analysis (COAs).

5.2.2 QC Inspector compares the raw material lot numbers on the batch record to the lot numbers on the COAs to ensure traceability.

5.2.3 QC Inspector verifies that the quantities of raw materials used in the batch are within the acceptable limits specified in the batch record.

5.2.4 QC Inspector verifies that the raw materials were properly stored and handled according to the manufacturer's recommendations and company SOPs.

5.2.5 QC Inspector verifies the results of any identity testing performed on the raw materials.

5.2.6 If dispensing of raw materials was involved, the QC Inspector verifies the dispensing records to ensure the correct materials and quantities were dispensed.

5.3 In-Process Control Verification

5.3.1 QC Inspector verifies that all in-process controls were performed according to the approved batch record and relevant SOPs.

5.3.2 QC Inspector reviews the results of all in-process testing to ensure that they meet the established specifications. This includes reviewing data from equipment such as the SFT-02 for particle size analysis.

5.3.3 QC Inspector verifies that any deviations from the approved process were properly documented and investigated.

5.3.4 QC Inspector verifies that all equipment used in the manufacturing process was properly calibrated and maintained. This includes reviewing the calibration records for equipment such as the BLN-04 blender and the TCP-01 tablet press.

5.3.5 QC Inspector verifies that environmental monitoring was performed, if applicable, and that the results are within acceptable limits.

5.3.6 QC Inspector verifies that the batch record includes documentation of equipment cleaning and sanitization.

5.4 Manufacturing Process Verification

5.4.1 QC Inspector reviews the batch record to ensure that the manufacturing process was performed according to the approved batch record and relevant SOPs.

5.4.2 QC Inspector verifies that all critical process parameters (e.g., temperature, pressure, mixing speed) were within the acceptable limits.

5.4.3 QC Inspector verifies that all process steps were completed in the correct sequence and within the specified timeframes.

5.4.4 QC Inspector reviews any documentation of process deviations or unplanned events.

5.4.5 QC Inspector verifies that the yield of the batch is within the acceptable limits. This should include a mass balance calculation and verification against the theoretical yield.

5.5 Finished Product Testing Verification

5.5.1 QC Inspector verifies that all required finished product testing was performed according to the approved batch record and relevant SOPs.

5.5.2 QC Inspector reviews the results of all finished product testing to ensure that they meet the established specifications.

5.5.3 QC Inspector verifies that the testing was performed by qualified personnel using validated methods.

5.5.4 QC Inspector verifies that the finished product samples were properly stored and handled.

5.5.5 QC Inspector verifies that the finished product is within its expiry date.

5.6 Deviation and Investigation Review

5.6.1 QC Inspector reviews all deviations and investigations documented in the batch record.

5.6.2 QC Inspector verifies that the deviations were properly investigated and that the root cause was identified.

5.6.3 QC Inspector verifies that appropriate corrective and preventive actions (CAPA) were implemented to prevent recurrence of the deviations.

5.6.4 QC Inspector evaluates the impact of the deviations on product quality and safety.

5.6.5 QC Inspector consults with the QA Manager to determine the acceptability of the deviations.

5.7 Batch Record Completion and Approval

5.7.1 QC Inspector completes the batch record review checklist, documenting all findings and observations.

5.7.2 QC Inspector provides the completed batch record and checklist to the QA Manager for review and approval.

5.7.3 QA Manager reviews the batch record and checklist, and evaluates the overall quality and compliance of the batch.

5.7.4 QA Manager verifies that all deviations have been adequately addressed and that the product meets all specifications.

5.7.5 QA Manager approves or rejects the batch based on the review findings. The approval or rejection is documented in the batch record.

5.7.6 If the batch is approved, the QA Manager signs and dates the batch record, indicating final batch release.

5.7.7 If the batch is rejected, the QA Manager documents the reason for rejection and initiates appropriate corrective actions. The Head of QA is notified of the rejection.

5.7.8 Released batch records are stored securely according to the company's document retention policy.

6.0 POST-BATCH RECORD REVIEW ACTIVITIES

6.1 The approved batch record is archived according to the document retention policy.

6.2 The approved batch is released for distribution.

6.3 Trend analysis is performed on the data collected during the batch record review process to identify any potential areas for improvement. The QA Manager is responsible for this task.

6.4 Corrective and preventive actions (CAPA) are implemented as necessary to address any systemic issues identified during the batch record review process. The QA Manager oversees the CAPA process.

6.5 The effectiveness of the CAPA actions is evaluated to ensure that they are preventing recurrence of the identified issues.

6.6 Training is provided to personnel on any changes to the batch record review process or related SOPs.

7.0 SAFETY PRECAUTIONS

7.1 All personnel involved in the batch record review process must be trained on the relevant SOPs and safety procedures.

7.2 Appropriate personal protective equipment (PPE) must be worn at all times when handling batch records and associated documentation.

7.3 All work areas must be kept clean and organized.

7.4 Any spills or accidents must be reported immediately to the supervisor.

7.5 When verifying data against computer systems, follow proper ergonomic practices to prevent strain and injury.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
Reviewed by (QA):	_____	_____	_____
Approved by (Head QA):	_____	_____	_____

Document Control Information

Document ID: SOP-QA-013

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System