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Title:	Annual Product Quality Review (APQR) Compilation	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Annual Product Quality Review (APQR) Compilation

Category: Quality Assurance

Standard Operating Procedure (SOP)

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Department: Quality Assurance

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1.0 PURPOSE

This procedure defines the methodology for compiling the Annual Product Quality Review (APQR) for all products manufactured at NovaThera Pharmaceuticals, ensuring compliance with Good Manufacturing Practices (GMP) and regulatory requirements. The APQR serves to verify the consistency of the existing manufacturing process, highlighting trends, identifying potential areas for improvement, and confirming the suitability of current specifications and controls for pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all medicinal products manufactured by NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, encompassing all dosage forms and strengths. It includes the collection, collation, evaluation, and reporting of data related to starting materials, packaging materials, in-process controls, finished product testing, deviations, complaints, recalls, returns, and stability monitoring for the period under review (typically a calendar year). This procedure excludes equipment maintenance and calibration, which are covered under separate SOPs.

3.0 RESPONSIBILITY

QC Inspector: Collects and compiles relevant data related to raw materials, packaging materials, in-process controls, finished product testing, and stability studies. Verifies the accuracy and completeness of the data.

Production Supervisor: Collects and compiles data related to production processes, deviations, complaints, recalls, and returns related to the products manufactured. Provides explanations for any deviations or trends observed.

QA Manager: Oversees the APQR process, ensures adherence to this SOP, reviews the compiled data and reports, identifies trends and potential issues, and proposes corrective and preventive actions (CAPA).

Head of QA: Approves the final APQR report and ensures that all identified CAPAs are implemented and tracked to completion. Ensures compliance with regulatory requirements and GMP guidelines.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, laboratory coat, gloves.

Equipment: Computer with access to the Electronic Quality Management System (eQMS), data analysis software (e.g., Microsoft Excel), printer.

Documentation: Batch Manufacturing Records (BMRs), Batch Packaging Records (BPRs), Raw Material Certificates of Analysis (CoAs), Packaging Material CoAs, In-Process Control data sheets, Finished Product Testing reports, Stability Study reports, Deviation reports, Complaint records, Recall records, Return records, Relevant SOPs, APQR Template (NTPL-APQR-001).

5.0 PROCEDURE

5.1 Data Collection and Compilation

5.1.1 The QC Inspector shall retrieve the relevant data pertaining to raw materials from the eQMS. This includes:

- List of all raw materials used in the manufacturing process during the review period.
- Number of batches of each raw material received.
- Results of all testing performed on each batch, including any out-of-specification (OOS) results.
- Vendor information for each raw material.
- Certificate of Analysis (CoA) for each batch of raw material.

5.1.2 The QC Inspector shall retrieve the relevant data pertaining to packaging materials from the eQMS. This includes:

• List of all packaging materials used in the manufacturing process during the review period.

• Number of batches of each packaging material received.

• Results of all testing performed on each batch, including any OOS results.

• Vendor information for each packaging material.

• Certificate of Analysis (CoA) for each batch of packaging material.

5.1.3 The QC Inspector shall retrieve the relevant in-process control data from the BMRs and eQMS for each product manufactured during the review period. This includes:

• Results of all in-process tests performed, such as blend uniformity, tablet hardness, disintegration time, and weight variation.

• Any deviations from established in-process control limits.

• Identification of the equipment used for in-process testing (e.g., Hardness Tester - HTS-01, Friability Tester - FRB-01).

5.1.4 The QC Inspector shall retrieve the relevant finished product testing data from the eQMS for each product manufactured during the review period. This includes:

• Results of all finished product tests performed, such as assay, impurity testing, dissolution, and identification.

• Any OOS results obtained during finished product testing.

• Reference standards used during testing, with their respective batch numbers and expiry dates.

• Identification of the analytical equipment used (e.g., HPLC - HPLC-05, UV Spectrophotometer - UV-02).

5.1.5 The QC Inspector shall retrieve the relevant stability study data from the eQMS for each product manufactured during the review period. This includes:

• Results of all stability tests performed at various time points and storage conditions.

• Any OOS results or significant trends observed during stability studies.

• Stability protocols used and deviations from the protocols.

• Identification of stability chambers used and their respective temperature/humidity settings (e.g., Stability Chamber 25°C/60%RH - STC-01).

5.1.6 The Production Supervisor shall retrieve the relevant production data from the BMRs and eQMS for each product manufactured during the review period. This includes:

• Batch numbers and sizes of all batches manufactured.

• Manufacturing dates for each batch.

• Yields of each batch.

• Information on any process deviations encountered during manufacturing (including equipment malfunction: e.g. BLN-04, TCP-01, SFT-02)

• Any rework or reprocessing performed on any batch.

5.1.7 The Production Supervisor shall retrieve the relevant data on complaints, recalls, and returns from the eQMS for each product manufactured during the review period. This includes:

• Number and nature of complaints received.

• Results of investigations into complaints.

• Number and reason for any recalls.

• Number and reason for any returns.

5.1.8 All collected data shall be compiled into the APQR template (NTPL-APQR-001) electronically.

5.2 Data Analysis and Trend Identification

5.2.1 The QA Manager shall review the compiled data to identify any trends or patterns. This includes:

• Evaluating trends in raw material quality and supplier performance.

• Analyzing trends in in-process control results to identify potential process variations.

• Analyzing trends in finished product testing results to identify potential quality issues.

• Evaluating trends in stability data to ensure product shelf life is supported.

• Analyzing trends in deviations, complaints, recalls, and returns to identify potential systemic issues.

5.2.2 The QA Manager shall perform statistical analysis on the data as needed to identify significant trends or outliers.

5.2.3 The QA Manager shall compare the data from the current review period with data from previous review periods to identify any long-term trends or changes in product quality.

5.3 APQR Report Generation

5.3.1 The QA Manager shall prepare a draft APQR report using the APQR template (NTPL-APQR-001). The report shall include the following sections:

• Executive Summary: A brief overview of the key findings of the APQR.

• Introduction: A description of the purpose and scope of the APQR.

• Product Description: A description of the product, including its dosage form, strength, and intended use.

• Raw Material Review: A summary of the raw material data, including any trends or issues identified.

• Packaging Material Review: A summary of the packaging material data, including any trends or issues identified.

• In-Process Control Review: A summary of the in-process control data, including any trends or issues identified.

• Finished Product Testing Review: A summary of the finished product testing data, including any trends or issues identified.

• Stability Study Review: A summary of the stability study data, including any trends or issues identified.

• Deviation Review: A summary of the deviation data, including any trends or issues identified.

• Complaint Review: A summary of the complaint data, including any trends or issues identified.

• Recall Review: A summary of the recall data, including any trends or issues identified.

• Return Review: A summary of the return data, including any trends or issues identified.

• Conclusions: A summary of the overall quality of the product during the review period.

• Recommendations: Any recommendations for improvements to the manufacturing process, controls, or specifications.

• CAPA Plan: A plan for implementing any corrective and preventive actions identified during the APQR.

5.3.2 The QA Manager shall review the draft APQR report with the Production Supervisor to obtain their input and feedback.

5.3.3 The QA Manager shall revise the draft APQR report based on the feedback received from the Production Supervisor.

5.4 APQR Report Approval and Distribution

5.4.1 The QA Manager shall submit the final APQR report to the Head of QA for approval.

5.4.2 The Head of QA shall review the APQR report to ensure that it is complete, accurate, and compliant with GMP requirements.

5.4.3 The Head of QA shall approve the APQR report.

5.4.4 A copy of the approved APQR report shall be distributed to the following departments:

- Production
- Quality Control
- Regulatory Affairs
- Supply Chain

5.5 CAPA Implementation and Tracking

5.5.1 The responsible departments shall implement the CAPAs identified in the APQR report according to the CAPA plan.

5.5.2 The QA Manager shall track the progress of the CAPA implementation and ensure that all CAPAs are completed in a timely manner.

5.5.3 The QA Manager shall document the completion of each CAPA in the eQMS.

5.5.4 The effectiveness of the implemented CAPAs shall be evaluated and documented.

6.0 POST-APQR ACTIVITIES

6.1 The QA Manager shall archive the approved APQR report and all supporting documentation in accordance with the document retention policy.

6.2 The QA Manager shall use the information in the APQR report to identify areas for continuous improvement in the manufacturing process and quality control systems.

6.3 The QA Manager shall present the key findings of the APQR report to senior management.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE, including safety glasses, laboratory coat, and gloves, when handling chemicals or working in the laboratory.

7.2 Follow all safety procedures outlined in the relevant SOPs.

7.3 Report any spills or accidents to the immediate supervisor immediately.

7.4 Ensure that all equipment is properly maintained and calibrated.

7.5 Use caution when handling data and ensure data integrity is maintained at all times.

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):	_____	_____	_____

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