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Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
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Preventive Maintenance Program

Category: Engineering & Maintenance

Standard Operating Procedure (SOP)

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Department: Engineering & Maintenance

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1.0 PURPOSE

This procedure establishes a comprehensive Preventive Maintenance Program for NovaThera Pharmaceuticals Pvt. Ltd. to ensure all equipment used in pharmaceutical manufacturing operates efficiently, reliably, and safely, thereby minimizing equipment downtime, maintaining product quality, and complying with current Good Manufacturing Practices (cGMP).

2.0 SCOPE

This SOP applies to all equipment and instruments used in the manufacturing, processing, packaging, testing, and storage of pharmaceutical products at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This includes, but is not limited to, production equipment, laboratory instruments, HVAC systems, water systems, and facility infrastructure, regardless of the product or batch being manufactured. It excludes personal protective equipment (PPE) maintenance, which is covered under a separate SOP.

3.0 RESPONSIBILITY

QC Inspector: Performs visual inspections and functional checks as outlined in the preventive maintenance schedule. Reports any deviations or abnormalities to the Production Supervisor

and QA Manager.

Production Supervisor: Oversees the implementation of the Preventive Maintenance Program within the production area. Ensures that maintenance activities are performed according to the schedule and SOP. Coordinates with the maintenance team and QA Manager for necessary repairs and adjustments. Verifies that equipment is clean and ready for use after maintenance.

QA Manager: Reviews and approves the Preventive Maintenance schedule. Ensures that all maintenance activities are documented properly and that deviations are investigated and resolved. Monitors the effectiveness of the Preventive Maintenance Program and recommends improvements.

Head of QA: Approves the SOP for the Preventive Maintenance Program and any revisions. Ensures that the program complies with cGMP regulations and company policies.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, gloves (appropriate for the task), safety shoes, hearing protection (as required), appropriate respiratory protection (as required).

Equipment: Maintenance tools (wrench sets, screwdrivers, multimeters, lubrication equipment, cleaning supplies), calibration standards, measuring instruments (calipers, micrometers), specialized tools for specific equipment (e.g., torque wrench for BLN-04), vibration analyzer, thermal imaging camera.

Documentation: Preventive Maintenance Schedule, Equipment Logbooks, Maintenance Request Forms, Deviation Reports, Calibration Certificates, Cleaning Logs, SOPs for specific maintenance tasks (e.g., lubrication, filter replacement), Spare Parts Inventory List.

5.0 PROCEDURE

5.1 Development of Preventive Maintenance Schedule

5.1.1 The Engineering & Maintenance Department shall develop a Preventive Maintenance Schedule based on manufacturer recommendations, equipment criticality, historical data, and regulatory requirements.

5.1.2 The schedule shall include the following information for each piece of equipment: Equipment Name, Equipment Code (e.g., BLN-04, TCP-01, SFT-02), Location, Maintenance Task, Frequency (e.g., daily, weekly, monthly, quarterly, annually), Responsible Person (role), Required Materials & Equipment, and SOP Reference (if applicable).

5.1.3 The frequency of maintenance tasks shall be determined based on the equipment's usage, operating conditions, and manufacturer's recommendations.

5.1.4 The Preventive Maintenance Schedule shall be reviewed and approved by the QA Manager and Head of QA annually.

5.1.5 The Preventive Maintenance Schedule shall be readily accessible to all relevant personnel.

5.2 Implementation of Preventive Maintenance

5.2.1 The Production Supervisor shall ensure that maintenance tasks are performed according to the Preventive Maintenance Schedule.

5.2.2 Before starting any maintenance task, the Engineering & Maintenance Department shall review the equipment logbook to check for any outstanding issues or previous maintenance records.

5.2.3 The Engineering & Maintenance Department shall gather all necessary materials, equipment, and documentation before starting the maintenance task.

5.2.4 The Engineering & Maintenance Department shall ensure that the equipment is properly isolated and locked out/tagged out (LOTO) according to the company's LOTO procedure before performing any maintenance.

5.2.5 The Engineering & Maintenance Department shall perform the maintenance task according to the applicable SOP or manufacturer's instructions.

5.2.6 During the maintenance task, the Engineering & Maintenance Department shall visually inspect the equipment for any signs of wear,

damage, or corrosion.

5.2.7 If any deviations or abnormalities are observed during the maintenance task, the Engineering & Maintenance Department shall immediately notify the Production Supervisor and QA Manager.

5.2.8 The QA Manager shall determine the appropriate course of action, which may include further investigation, repair, or replacement of the equipment.

5.2.9 All maintenance activities shall be documented in the Equipment Logbook, including the date, time, task performed, person performing the task, any deviations observed, and corrective actions taken.

5.2.10 After completing the maintenance task, the Engineering & Maintenance Department shall restore the equipment to its normal operating condition.

5.2.11 The Engineering & Maintenance Department shall verify that the equipment is functioning properly and that all safety devices are in place.

5.2.12 The Production Supervisor shall ensure that the equipment is clean and ready for use before releasing it back to production.

5.3 Lubrication Program

5.3.1 All equipment requiring lubrication shall be included in the Lubrication Program.

5.3.2 The Engineering & Maintenance Department shall develop a Lubrication Schedule that specifies the type of lubricant, the lubrication points, and the frequency of lubrication for each piece of equipment.

5.3.3 The Lubrication Schedule shall be based on the manufacturer's recommendations and the equipment's operating conditions.

5.3.4 Only approved lubricants shall be used in the Lubrication Program.

5.3.5 Lubricants shall be stored in a clean and dry area.

5.3.6 The Engineering & Maintenance Department shall ensure that lubricants are properly labeled and that Material Safety Data Sheets (MSDS) are readily available.

5.3.7 The Engineering & Maintenance Department shall lubricate the equipment according to the Lubrication Schedule and the applicable SOP.

5.3.8 All lubrication activities shall be documented in the Equipment Logbook.

5.4 Calibration Program

5.4.1 All measuring instruments and equipment requiring calibration shall be included in the Calibration Program.

5.4.2 The QA Department shall develop a Calibration Schedule that specifies the calibration frequency and the calibration method for each instrument.

5.4.3 The Calibration Schedule shall be based on the manufacturer's recommendations, regulatory requirements, and the equipment's intended use.

5.4.4 All calibrations shall be performed using calibrated standards traceable to national or international standards.

5.4.5 Calibrations shall be performed by qualified personnel.

5.4.6 Calibration certificates shall be maintained for all calibrated instruments.

5.4.7 If an instrument is found to be out of calibration, the QA Manager shall be notified immediately.

5.4.8 The QA Manager shall determine the appropriate course of action, which may include adjusting the instrument, repairing the instrument, or removing the instrument from service.

5.4.9 All calibration activities shall be documented in the Equipment Logbook and Calibration Certificates.

5.5 Filter Replacement Program

5.5.1 All filters used in air handling units (AHUs), water systems, and other critical equipment shall be included in the Filter Replacement Program.

5.5.2 The Engineering & Maintenance Department shall develop a Filter Replacement Schedule that specifies the filter type, the replacement frequency, and the replacement procedure for each filter.

5.5.3 The Filter Replacement Schedule shall be based on the manufacturer's recommendations, regulatory requirements, and the equipment's operating conditions.

5.5.4 Only approved filters shall be used in the Filter Replacement Program.

5.5.5 Filters shall be stored in a clean and dry area.

5.5.6 The Engineering & Maintenance Department shall replace the filters according to the Filter Replacement Schedule and the applicable SOP.

5.5.7 All filter replacement activities shall be documented in the Equipment Logbook.

5.5.8 Used filters shall be disposed of according to the company's waste disposal procedure.

5.6 Vibration Monitoring Program

5.6.1 Critical rotating equipment (e.g., blenders BLN-04, tablet presses TCP-01, pumps) shall be included in the Vibration Monitoring Program.

5.6.2 The Engineering & Maintenance Department shall use a vibration analyzer to monitor the vibration levels of the equipment.

5.6.3 Vibration readings shall be taken according to a predetermined schedule.

5.6.4 Vibration data shall be analyzed to identify any potential problems.

5.6.5 If abnormal vibration levels are detected, the Engineering & Maintenance Department shall investigate the cause and take corrective action.

5.6.6 All vibration monitoring activities shall be documented in the Equipment Logbook.

5.7 Thermal Imaging Program

5.7.1 Electrical panels, motors, and other critical equipment shall be included in the Thermal Imaging Program.

5.7.2 The Engineering & Maintenance Department shall use a thermal imaging camera to inspect the equipment for hotspots.

5.7.3 Thermal imaging inspections shall be performed according to a predetermined schedule.

5.7.4 Thermal images shall be analyzed to identify any potential problems.

5.7.5 If hotspots are detected, the Engineering & Maintenance Department shall investigate the cause and take corrective action.

5.7.6 All thermal imaging activities shall be documented in the Equipment Logbook.

6.0 POST-MAINTENANCE ACTIVITIES

6.1 After completion of any maintenance activity, the Engineering & Maintenance Department shall ensure that the equipment is properly cleaned and sanitized according to the applicable cleaning SOP.

6.2 The Engineering & Maintenance Department shall verify that all tools and equipment have been removed from the area.

6.3 The Engineering & Maintenance Department shall update the Equipment Logbook with all relevant information, including the date, time, task performed, person performing the task, any deviations observed, and corrective actions taken.

6.4 The Production Supervisor shall review the Equipment Logbook to verify that the maintenance activity has been completed properly.

6.5 The Production Supervisor shall ensure that the equipment is ready for use before releasing it back to production.

6.6 The QA Manager shall periodically review the Equipment Logbooks to monitor the effectiveness of the Preventive Maintenance Program.

7.0 SAFETY PRECAUTIONS

- 7.1 All personnel involved in maintenance activities shall wear appropriate PPE, including safety glasses, gloves, and safety shoes.
- 7.2 Lockout/Tagout (LOTO) procedures shall be followed before performing any maintenance on electrical equipment or equipment with moving parts.
- 7.3 Only qualified personnel shall perform maintenance on electrical equipment.
- 7.4 Flammable materials shall be stored in a designated area away from sources of ignition.
- 7.5 All spills shall be cleaned up immediately.
- 7.6 Material Safety Data Sheets (MSDS) shall be readily available for all chemicals used in maintenance activities.
- 7.7 Ensure proper ventilation when working with chemicals.
- 7.8 Report any unsafe conditions to the Production Supervisor immediately.
- 7.9 Emergency contact information shall be readily available.
- 7.10 Hearing protection shall be worn when working in noisy environments.
- 7.11 Respiratory protection shall be worn when working with dust or fumes.

8.0 APPROVALS

Prepared By: Engineering Manager

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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