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Operation and Maintenance of the HVAC System for Manufacturing Areas

Category: Engineering & Maintenance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Engineering & Maintenance

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1.0 PURPOSE

This procedure outlines the standardized process for the operation, maintenance, and monitoring of the Heating, Ventilation, and Air Conditioning (HVAC) system to ensure a controlled environment within the manufacturing areas of NovaThera Pharmaceuticals, thereby maintaining product quality and complying with Good Manufacturing Practices (GMP) for pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all personnel responsible for the operation, maintenance, and monitoring of the HVAC system serving the manufacturing areas, including but not limited to production areas, storage areas for raw materials (RWM-01) and finished goods (FGS-01), and quality control laboratories (QCL-01) at NovaThera Pharmaceuticals. It covers routine operation, preventative maintenance, troubleshooting, and documentation procedures for the HVAC system, ensuring environmental control parameters are maintained for all applicable materials and products.

3.0 RESPONSIBILITY

QC Inspector:

- Performs routine environmental monitoring (temperature, humidity, differential pressure) as per established schedules and records data accurately.
- Reports any deviations from specified limits to the Production Supervisor and QA Manager immediately.
- Participates in investigations related to environmental control deviations.

Production Supervisor:

- Ensures that the HVAC system is operating within specified parameters before the commencement of any manufacturing activity.
- Monitors HVAC system performance during manufacturing operations and reports any abnormalities to the Engineering & Maintenance department.
- Collaborates with the Engineering & Maintenance department to schedule routine maintenance activities to minimize disruption to production schedules.

QA Manager:

- Reviews and approves all documentation related to HVAC system operation, maintenance, and monitoring.
- Ensures that the HVAC system is validated and that re-validation is performed at appropriate intervals.
- Investigates deviations related to environmental control and implements corrective and preventive actions (CAPA).
- Provides training to relevant personnel on GMP requirements related to HVAC system operation.

Head of QA:

- Has overall responsibility for ensuring compliance with GMP regulations related to the HVAC system.
- Approves all SOPs related to HVAC system operation, maintenance, and monitoring.
- Oversees the implementation of CAPA related to environmental control deviations.
- Ensures that the HVAC system is included in internal and external audits.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or latex, as appropriate)
- Hearing protection (where noise levels exceed 85 dBA)
- Safety shoes
- Dust mask/respirator (as required for specific maintenance tasks)

Equipment:

- Temperature and humidity data loggers (TEM-01, HUM-01)
- Differential pressure gauges (DPG-01)
- Air velocity meters (AVM-01)
- Manometer
- Multimeter
- Toolkit (general maintenance tools)
- Calibration standards for temperature, humidity, and pressure
- Air filter replacements (various sizes and types)
- Cleaning supplies (approved for use in cleanroom environments)
- Leak detection spray
- Refrigerant gauges (RGS-01)
- Vacuum pump
- Nitrogen cylinder
- Recovery unit

Documentation:

- HVAC System Operation Logbook (HVAC-LOG-001)
- HVAC System Maintenance Logbook (HVAC-LOG-002)
- Environmental Monitoring Logbook (ENV-LOG-001)
- HVAC System Calibration Records (CAL-REC-001)
- HVAC System Validation Report (VAL-REP-001)
- Preventative Maintenance Schedule (PMS-ENG-001)
- Deviation Report Form (QA-FRM-001)
- Corrective Action/Preventive Action (CAPA) Form (QA-FRM-002)
- Equipment Usage Log (EUL-ENG-001)

5.0 PROCEDURE

5.1 Start-Up Procedure

5.1.1 The Engineering & Maintenance department verifies that all necessary pre-start checks have been completed as per the Preventative Maintenance Schedule (PMS-ENG-001).

5.1.2 The Engineering & Maintenance department visually inspects the HVAC system components (e.g., air handling units (AHU-01), chillers (CHL-01), cooling towers, ductwork) for any signs of damage or malfunction.

5.1.3 The Engineering & Maintenance department confirms that the air filters are clean and properly installed. If dirty, replace filters immediately as per section 5.4.

5.1.4 The Engineering & Maintenance department ensures that all access panels are securely closed and locked.

5.1.5 The Engineering & Maintenance department activates the HVAC system using the designated control panel, following the manufacturer's instructions.

5.1.6 The Engineering & Maintenance department monitors the system start-up, verifying that the supply and return fans are operating correctly.

5.1.7 The Engineering & Maintenance department verifies that the temperature and humidity control systems are functioning properly.

5.1.8 The Engineering & Maintenance department monitors differential pressure gauges (DPG-01) to ensure proper airflow direction between different areas (e.g., cleanroom to corridor).

5.1.9 The Production Supervisor verifies that the environmental conditions (temperature, humidity, differential pressure) within the manufacturing areas are within specified limits.

5.1.10 The Production Supervisor records the start-up time, date, and environmental conditions in the HVAC System Operation Logbook (HVAC-LOG-001).

5.1.11 The QC Inspector conducts initial environmental monitoring as per the Environmental Monitoring Schedule (ENV-MNT-001) and records the results in the Environmental Monitoring Logbook (ENV-LOG-001).

5.2 Routine Operation

5.2.1 The Production Supervisor continuously monitors the HVAC system performance during manufacturing operations.

5.2.2 The Production Supervisor verifies that the temperature and humidity levels are maintained within the specified ranges as defined in the batch manufacturing record (BMR).

5.2.3 The Production Supervisor checks the differential pressure between different areas at least once per shift, recording the readings in the HVAC System Operation Logbook (HVAC-LOG-001).

5.2.4 The QC Inspector performs routine environmental monitoring (temperature, humidity, microbial air sampling) as per the Environmental Monitoring Schedule (ENV-MNT-001) and records the results in the Environmental Monitoring Logbook (ENV-LOG-001).

5.2.5 The QC Inspector immediately reports any deviations from specified limits to the Production Supervisor and QA Manager.

5.2.6 The Engineering & Maintenance department addresses any alarms or unusual readings promptly, following the troubleshooting guidelines outlined in section 5.5.

5.2.7 The Engineering & Maintenance department documents all corrective actions taken in the HVAC System Maintenance Logbook (HVAC-LOG-002).

5.3 Preventative Maintenance

5.3.1 The Engineering & Maintenance department follows the Preventative Maintenance Schedule (PMS-ENG-001) to perform routine maintenance tasks on the HVAC system.

5.3.2 The Engineering & Maintenance department shuts down the relevant HVAC system components (e.g., AHU-01) before commencing maintenance activities, following lockout/tagout procedures.

5.3.3 The Engineering & Maintenance department visually inspects all HVAC system components for signs of wear, damage, or corrosion.

5.3.4 The Engineering & Maintenance department cleans or replaces air filters as required, following the procedures outlined in section 5.4.

5.3.5 The Engineering & Maintenance department lubricates moving parts (e.g., fan bearings, motor bearings) as per the manufacturer's recommendations.

5.3.6 The Engineering & Maintenance department checks and tightens all electrical connections.

5.3.7 The Engineering & Maintenance department calibrates temperature, humidity, and pressure sensors according to the Calibration Schedule (CAL-SCHED-001).

5.3.8 The Engineering & Maintenance department verifies the operation of dampers and actuators.

5.3.9 The Engineering & Maintenance department checks refrigerant levels in the chillers (CHL-01) and adds refrigerant as necessary, following proper handling procedures.

5.3.10 The Engineering & Maintenance department cleans cooling tower components to prevent scale buildup and microbial growth.

5.3.11 The Engineering & Maintenance department tests the emergency power supply to ensure proper operation in case of a power outage.

5.3.12 The Engineering & Maintenance department documents all maintenance activities performed in the HVAC System Maintenance Logbook (HVAC-LOG-002).

5.3.13 The Engineering & Maintenance department restarts the HVAC system after completing maintenance activities, following the start-up procedure outlined in section 5.1.

5.4 Air Filter Replacement

5.4.1 The Engineering & Maintenance department identifies the air filter(s) requiring replacement based on the Preventative Maintenance Schedule (PMS-ENG-001) or visual inspection.

5.4.2 The Engineering & Maintenance department shuts down the corresponding AHU-01.

5.4.3 The Engineering & Maintenance department wears appropriate PPE (safety glasses, gloves, dust mask/respirator).

5.4.4 The Engineering & Maintenance department carefully removes the used air filter(s), taking precautions to minimize dust and debris release.

5.4.5 The Engineering & Maintenance department places the used air filter(s) in a sealed plastic bag for proper disposal as per waste disposal procedures (SOP-EHS-001).

5.4.6 The Engineering & Maintenance department cleans the filter housing with a validated cleaning agent.

5.4.7 The Engineering & Maintenance department installs the new air filter(s), ensuring proper orientation and secure fit.

5.4.8 The Engineering & Maintenance department restarts the AHU-01.

5.4.9 The Engineering & Maintenance department records the air filter replacement in the HVAC System Maintenance Logbook (HVAC-LOG-002), including the date, filter type, and AHU-01 identification.

5.4.10 The Engineering & Maintenance department updates the filter replacement schedule.

5.5 Troubleshooting

5.5.1 The Engineering & Maintenance department investigates any alarms, unusual readings, or reports of HVAC system malfunction.

5.5.2 The Engineering & Maintenance department reviews the HVAC System Operation Logbook (HVAC-LOG-001) and HVAC System Maintenance Logbook (HVAC-LOG-002) for relevant information.

5.5.3 The Engineering & Maintenance department uses appropriate diagnostic tools (e.g., multimeter, manometer, air velocity meter) to identify the cause of the problem.

5.5.4 The Engineering & Maintenance department consults the manufacturer's manuals and technical documentation for troubleshooting guidance.

5.5.5 The Engineering & Maintenance department follows established troubleshooting procedures for common problems, such as:

- Low airflow: Check for clogged filters, malfunctioning fans, or blocked ductwork.
- Temperature control issues: Check for malfunctioning sensors, faulty valves, or refrigerant leaks.
- Humidity control issues: Check for malfunctioning humidifiers or dehumidifiers.
- Pressure control issues: Check for leaking seals or damper malfunctions.

5.5.6 The Engineering & Maintenance department takes corrective actions to resolve the problem, such as:

- Replacing faulty components
- Repairing leaks
- Adjusting settings
- Cleaning or clearing obstructions

5.5.7 The Engineering & Maintenance department documents all troubleshooting steps and corrective actions taken in the HVAC System Maintenance Logbook (HVAC-LOG-002).

5.5.8 The Engineering & Maintenance department verifies that the HVAC system is functioning properly after the corrective actions have been completed.

5.5.9 If the problem cannot be resolved, the Engineering & Maintenance department escalates the issue to a qualified HVAC technician or service provider.

5.6 Shut-Down Procedure

5.6.1 The Production Supervisor notifies the Engineering & Maintenance department of the need to shut down the HVAC system (e.g., at the end of a production run).

5.6.2 The Engineering & Maintenance department gradually reduces the HVAC system output to minimize stress on the equipment.

5.6.3 The Engineering & Maintenance department shuts down the HVAC system components (e.g., AHU-01, chillers) in a controlled manner, following the manufacturer's instructions.

5.6.4 The Engineering & Maintenance department secures all access panels and locks.

5.6.5 The Engineering & Maintenance department records the shut-down time and date in the HVAC System Operation Logbook (HVAC-LOG-001).

5.6.6 The Engineering & Maintenance department performs a final inspection of the HVAC system to ensure that all components are properly shut down and secured.

6.0 POST-MAINTENANCE ACTIVITIES

6.1 Following any maintenance or repair activity, the Engineering & Maintenance department completes all relevant documentation in the HVAC System Maintenance Logbook (HVAC-LOG-002), including details of the work performed, parts replaced, and any deviations encountered.

6.2 The Engineering & Maintenance department notifies the Production Supervisor and QA Manager that the maintenance is complete and the HVAC system is ready for operation.

6.3 The Production Supervisor verifies that the manufacturing areas are clean and free of any debris from the maintenance activities.

6.4 The QC Inspector performs environmental monitoring to verify that the environmental conditions within the manufacturing areas are within specified limits before resuming production activities.

6.5 The QA Manager reviews the maintenance documentation and environmental monitoring data to ensure that all requirements have been met.

6.6 If any deviations are identified, the QA Manager initiates a deviation investigation and implements corrective and preventive actions (CAPA) as necessary.

7.0 SAFETY PRECAUTIONS

7.1 All personnel working on the HVAC system must wear appropriate PPE, including safety glasses, gloves, hearing protection, and safety shoes.

7.2 Follow lockout/tagout procedures before performing any maintenance or repair work on the HVAC system.

7.3 Use caution when working with electrical components. Ensure that power is disconnected before working on electrical equipment.

7.4 Use caution when working with refrigerants. Follow proper handling procedures to prevent skin contact and inhalation.

7.5 Use caution when working at heights. Use ladders or scaffolding that are in good condition and properly secured.

7.6 Be aware of potential hazards, such as moving parts, hot surfaces, and sharp edges.

7.7 Report any unsafe conditions or practices to the Engineering & Maintenance department immediately.

7.8 Refer to the Material Safety Data Sheets (MSDS) for all chemicals used in the maintenance of the HVAC system.

7.9 Ensure adequate ventilation when working in confined spaces.

7.10 Dispose of used air filters and other waste materials properly, following waste disposal procedures (SOP-EHS-001).

8.0 APPROVALS

Prepared By: Engineering Manager

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

Document Approval

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