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General Laboratory Practices and Safety

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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Department: Quality Control

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1.0 PURPOSE

This procedure outlines the standard operating practices for ensuring safety, data integrity, and maintaining a cGMP-compliant environment within the Quality Control laboratory at NovaThera Pharmaceuticals during pharmaceutical manufacturing. It provides guidelines for proper laboratory conduct, equipment handling, documentation, and waste disposal to ensure the reliability and accuracy of analytical results.

2.0 SCOPE

This SOP applies to all personnel working within the Quality Control laboratory at NovaThera Pharmaceuticals, including QC Inspectors, analysts, supervisors, and any other personnel authorized to enter and work in the laboratory. It covers all activities related to the receipt, storage, testing, and reporting of raw materials, in-process materials, finished products, and stability samples. This SOP is applicable to all pharmaceutical products manufactured by NovaThera Pharmaceuticals.

3.0 RESPONSIBILITY

QC Inspector:

- Adheres to the guidelines outlined in this SOP.
- Reports any deviations or non-conformances to the QC Supervisor.
- Maintains accurate and complete records of all activities performed.
- Ensures proper handling, storage, and disposal of samples and reagents.
- Performs routine cleaning and maintenance of laboratory equipment.
- Wears appropriate PPE at all times.

Production Supervisor:

- Ensures personnel are trained on this SOP and comply with its requirements.
- Provides necessary resources and support for the implementation of this SOP.
- Reports any safety concerns or violations to the QA Manager.
- Verifies the correct usage and storage of materials.

QA Manager:

- Reviews and approves this SOP.
- Ensures the SOP is implemented and followed correctly.
- Investigates any deviations or non-conformances related to this SOP.
- Conducts periodic audits to verify compliance with this SOP.
- Approves corrective and preventive actions (CAPA) related to this SOP.

Head of QA:

- Provides overall oversight for the implementation and compliance with this SOP.
- Approves changes to this SOP.
- Resolves any disputes related to this SOP.
- Ensures that the SOP aligns with cGMP regulations and company policies.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses or goggles
- Laboratory coats
- Disposable gloves (nitrile or latex)
- Face masks (when required)
- Closed-toe shoes
- Chemical-resistant gloves (when handling hazardous materials)

Equipment:

- Analytical balances (BAL-01, BAL-02)

- pH meter (PHM-01)
- UV-Vis Spectrophotometer (UVS-01)
- High-Performance Liquid Chromatography (HPLC) system (HPLC-01, HPLC-02)
- Gas Chromatography (GC) system (GC-01)
- Dissolution apparatus (DIS-01)
- Disintegration tester (DST-01)
- Tablet hardness tester (HRD-01)
- Karl Fischer titrator (KFT-01)
- Incubators (INC-01, INC-02)
- Autoclave (AUT-01)
- Refrigerator (REF-01, REF-02)
- Freezer (FRZ-01)
- Fume hoods (FHD-01, FHD-02)
- Vortex mixer (VRX-01)
- Sonicator (SNC-01)
- Microscope (MIC-01)
- Pipettes (various volumes)
- Volumetric flasks (various volumes)
- Beakers (various sizes)
- Graduated cylinders (various sizes)
- Drying oven (DRY-01)
- Sieves (various mesh sizes, SFT-02)

Documentation:

- Laboratory notebooks
- Equipment usage logs
- Calibration records
- Training records
- Deviation reports
- Incident reports
- Analytical test reports
- Material Safety Data Sheets (MSDS)
- SOPs

5.0 PROCEDURE

5.1 General Laboratory Conduct

5.1.1 The QC Inspector must ensure that the laboratory is clean and organized at all times.

5.1.2 The QC Inspector must wipe down work surfaces with a suitable disinfectant before and after each use.

5.1.3 The QC Inspector must label all containers clearly with the contents, date, and initials.

5.1.4 The QC Inspector must store all chemicals and reagents in their designated storage areas, following safety guidelines and compatibility requirements.

5.1.5 Eating, drinking, smoking, and applying cosmetics are prohibited in the laboratory.

5.1.6 The QC Inspector must properly dispose of all waste materials according to the waste disposal SOP.

5.1.7 The QC Inspector must report any spills, accidents, or unsafe conditions to the QC Supervisor immediately.

5.1.8 The QC Inspector must adhere to all applicable safety regulations and procedures.

5.1.9 The QC Inspector must document all laboratory activities in the appropriate laboratory notebook or electronic system in real-time.

5.1.10 The QC Inspector must calibrate and maintain all laboratory equipment according to the equipment calibration schedule.

5.1.11 The QC Inspector must store all samples properly to maintain their integrity and prevent degradation.

5.1.12 The QC Inspector must use only approved and validated analytical methods.

5.1.13 The QC Inspector must ensure all data is backed up regularly according to the data management SOP.

5.1.14 The QC Inspector must wear appropriate PPE (safety glasses, lab coat, gloves) at all times when in the laboratory.

5.1.15 The QC Inspector must review MSDS for all chemicals prior to use.

5.1.16 The QC Inspector must ensure all equipment has been qualified before use.

5.1.17 The QC Inspector must record equipment usage in the equipment logbook.

5.2 Equipment Handling and Maintenance

5.2.1 Prior to using any equipment, the QC Inspector must verify that it is calibrated and in good working order by checking the calibration sticker or logbook.

5.2.2 The QC Inspector must follow the manufacturer's instructions for operating each piece of equipment.

5.2.3 The QC Inspector must clean the equipment after each use according to the equipment-specific cleaning SOP.

5.2.4 The QC Inspector must record all equipment usage in the equipment logbook, including the date, time, user, and purpose.

5.2.5 The QC Inspector must report any equipment malfunctions or failures to the QC Supervisor immediately.

5.2.6 The QC Inspector must not attempt to repair any equipment without proper training and authorization.

5.2.7 The QC Inspector must ensure that preventive maintenance is performed on all equipment according to the maintenance schedule.

5.2.8 The QC Inspector must maintain a separate logbook for each piece of equipment to record all maintenance and repair activities.

5.2.9 For analytical balances (BAL-01, BAL-02), the QC Inspector must level the balance, check the calibration using certified weights, and document the results in the balance logbook before use.

5.2.10 For the UV-Vis Spectrophotometer (UVS-01), the QC Inspector must perform a wavelength accuracy check using a suitable reference standard before use.

5.2.11 For the HPLC system (HPLC-01, HPLC-02), the QC Inspector must equilibrate the column with the mobile phase, check the system suitability, and document the results in the HPLC system logbook before use.

5.2.12 For the GC system (GC-01), the QC Inspector must check the carrier gas pressure, column temperature, and detector settings before use.

5.2.13 The QC Inspector must follow specific SOPs for operating and maintaining specialized equipment like the Dissolution apparatus (DIS-01), Disintegration tester (DST-01), Tablet hardness tester (HRD-01), and Karl

Fischer titrator (KFT-01).

5.3 Sample Handling and Storage

5.3.1 The QC Inspector must receive samples from the appropriate department with a completed sample submission form.

5.3.2 The QC Inspector must verify that the sample is properly labeled and matches the information on the submission form.

5.3.3 The QC Inspector must assign a unique laboratory sample number to each sample and record it in the sample logbook.

5.3.4 The QC Inspector must store samples according to the specified storage conditions (temperature, humidity, light exposure) as indicated on the sample label or in the testing protocol.

5.3.5 The QC Inspector must maintain a temperature monitoring system for refrigerators (REF-01, REF-02) and freezers (FRZ-01) and document the temperature readings daily.

5.3.6 The QC Inspector must track the storage location of each sample in the sample logbook or electronic system.

5.3.7 The QC Inspector must withdraw samples for testing according to the testing schedule and record the date, time, and quantity withdrawn in the sample logbook.

5.3.8 The QC Inspector must return any unused portion of the sample to its designated storage location after testing.

5.3.9 The QC Inspector must dispose of expired or exhausted samples according to the waste disposal SOP.

5.3.10 The QC Inspector must maintain a sample retention program as defined by the QA Manager, storing retain samples under specified conditions.

5.3.11 The QC Inspector must properly document the receipt, storage, withdrawal, and disposal of samples in the sample logbook.

5.4 Documentation Practices

5.4.1 The QC Inspector must record all laboratory activities in real-time in a laboratory notebook or electronic system.

5.4.2 The QC Inspector must use indelible ink (blue or black) for all written entries.

5.4.3 The QC Inspector must make corrections by drawing a single line through the incorrect entry, initialing and dating the correction, and providing a brief explanation.

5.4.4 The QC Inspector must not use white-out or correction fluid to cover up errors.

5.4.5 The QC Inspector must sign and date each page of the laboratory notebook.

5.4.6 The QC Inspector must maintain a separate logbook for each piece of equipment, recording all usage, maintenance, and calibration activities.

5.4.7 The QC Inspector must file all documentation (laboratory notebooks, equipment logbooks, analytical test reports, deviation reports) in a secure and organized manner.

5.4.8 The QC Inspector must comply with all data integrity principles, including ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate).

5.4.9 The QC Inspector must ensure that all data is backed up regularly according to the data management SOP.

5.4.10 The QC Inspector must review all documentation for completeness and accuracy before submitting it to the QC Supervisor.

5.4.11 The QC Inspector must follow the document control SOP for creating, revising, and approving documents.

6.0 POST-ACTIVITY ACTIVITIES

6.1 The QC Inspector must clean the work area and equipment used during the procedure.

6.2 The QC Inspector must properly dispose of any waste generated during the procedure according to the waste disposal SOP.

6.3 The QC Inspector must store any remaining samples or materials in their designated storage locations.

6.4 The QC Inspector must complete all necessary documentation, including laboratory notebooks, equipment logbooks, and analytical test reports.

6.5 The QC Inspector must review the documentation for completeness and accuracy.

6.6 The QC Inspector must submit the completed documentation to the QC Supervisor for review.

6.7 The QC Inspector must report any deviations or non-conformances to the QC Supervisor.

6.8 The QC Inspector must participate in any investigations related to deviations or non-conformances.

6.9 The QC Inspector must implement any corrective and preventive actions (CAPA) assigned to them.

6.10 The QC Inspector must ensure that all equipment is turned off and properly secured before leaving the laboratory.

6.11 The QC Inspector must ensure that all safety hazards are addressed before leaving the laboratory.

6.12 The Production Supervisor reviews laboratory cleaning and documentation for accuracy and completeness, initiating any necessary corrective actions.

6.13 The QA Manager performs periodic audits of laboratory activities to ensure adherence to this SOP.

7.0 SAFETY PRECAUTIONS

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

7.2 Handle all chemicals and reagents with care and follow the instructions on the Material Safety Data Sheet (MSDS).

7.3 Work in a well-ventilated area, preferably under a fume hood, when handling volatile or hazardous chemicals.

7.4 Never pipette by mouth. Use a pipette aid or automatic pipette.

7.5 Do not eat, drink, smoke, or apply cosmetics in the laboratory.

7.6 Be aware of the location of safety equipment, such as fire extinguishers, eyewash stations, and safety showers.

7.7 In case of a spill, clean it up immediately according to the spill control SOP.

7.8 Report any accidents or injuries to the QC Supervisor immediately.

7.9 Properly dispose of all waste materials according to the waste disposal SOP.

7.10 Do not work alone in the laboratory if you are handling hazardous materials or performing potentially dangerous procedures.

7.11 Be aware of potential electrical hazards and take precautions to avoid electrical shocks.

7.12 Store flammable materials in designated flammable storage cabinets.

7.13 Never mix incompatible chemicals.

7.14 Follow all applicable safety regulations and procedures.

7.15 The QC Inspector must be properly trained on handling compressed gas cylinders and connecting/disconnecting regulators as per the gas cylinder safety SOP.

7.16 Use a cart to move heavy objects or chemicals.

7.17 In case of fire, activate the fire alarm and evacuate the building immediately.

7.18 If chemicals come into contact with skin or eyes, flush immediately with copious amounts of water and seek medical attention.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

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Document Approval

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