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Operation, Calibration, and Maintenance of the Dissolution Test Apparatus

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure outlines the standardized method for the proper operation, calibration, and maintenance of the dissolution test apparatus in the Quality Control Laboratory at NovaThera Pharmaceuticals Pvt. Ltd. This SOP ensures the reliable and reproducible performance of dissolution testing, a critical analytical procedure in pharmaceutical manufacturing. It establishes a consistent approach for generating accurate and compliant data, ensuring product quality and adherence to regulatory requirements.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to all Quality Control personnel involved in the operation, calibration, and maintenance of dissolution test apparatus (e.g., Apparatus 1, Apparatus 2, Apparatus 5) used for testing solid oral dosage forms, including tablets, capsules, and granules, at NovaThera Pharmaceuticals Pvt. Ltd. This SOP covers all dissolution testing equipment regardless of the specific product or batch being tested, ensuring consistent application of the procedure. It encompasses all aspects of the dissolution testing process, from equipment setup and operation to calibration, cleaning, and preventative maintenance.

3.0 RESPONSIBILITY

QC Inspector:

- Performs dissolution testing according to this SOP and approved test methods.
- Verifies the calibration status of the dissolution test apparatus prior to use.
- Documents all activities related to operation, calibration, and maintenance in the appropriate logbooks and forms.
- Reports any deviations, malfunctions, or out-of-specification (OOS) results to the Production Supervisor and QA Manager.
- Ensures proper cleaning and storage of dissolution apparatus components.
- Performs routine maintenance as outlined in this SOP.

Production Supervisor:

- Oversees the activities of the QC Inspector in relation to dissolution testing.
- Investigates any deviations, malfunctions, or OOS results reported by the QC Inspector.
- Ensures that all personnel are adequately trained on this SOP.
- Schedules and monitors the preventative maintenance of the dissolution test apparatus.

QA Manager:

- Reviews and approves this SOP.
- Ensures that this SOP is followed and that all activities are performed according to GMP requirements.
- Oversees investigations of deviations, malfunctions, or OOS results related to dissolution testing.
- Approves corrective and preventative actions (CAPA) related to dissolution testing.
- Ensures that adequate training records are maintained for all personnel involved in dissolution testing.
- Schedules and oversees periodic audits of the dissolution testing process.

Head of QA:

- Provides final approval for this SOP and any revisions.
- Ensures overall compliance with GMP and regulatory requirements for dissolution testing.
- Resolves any disputes or escalated issues related to dissolution testing.
- Oversees the overall quality assurance program for NovaThera Pharmaceuticals Pvt. Ltd.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses

- Laboratory coat
- Nitrile gloves

Equipment:

- Dissolution Test Apparatus (e.g., Hanson Research SR8+, Erweka DT 720, Varian VK 7000)
- Dissolution vessels (e.g., 1000 mL, 900 mL)
- Paddles (Apparatus 2)
- Baskets (Apparatus 1)
- Shafts for paddles and baskets
- Water bath or heating system
- Temperature probe (calibrated)
- pH meter (calibrated)
- Analytical balance (e.g., MET-01, MET-02, calibrated)
- Volumetric flasks and pipettes (calibrated)
- Filters (appropriate pore size for the test)
- HPLC system (e.g., HPC-01, HPC-02) or UV-Vis spectrophotometer (e.g., SPE-01, SPE-02)
- Degassing system (e.g., vacuum pump, helium sparging)

Documentation:

- Dissolution Test Apparatus Logbook (LOG-QC-007A)
- Dissolution Test Method (STM-XXX, where XXX is the specific method number)
- Calibration Certificates for temperature probe, pH meter, and analytical balance
- Deviation Report Form (FRM-QA-001)
- Out-of-Specification (OOS) Investigation Report Form (FRM-QA-002)

5.0 PROCEDURE

5.1 Preparation of Dissolution Media

5.1.1 The QC Inspector refers to the Dissolution Test Method (STM-XXX) for the specific requirements for the dissolution medium (e.g., pH, buffer concentration, volume).

5.1.2 Using a calibrated analytical balance (MET-01 or MET-02), weigh the required amount of each chemical specified in the Dissolution Test Method.

5.1.3 Transfer the weighed chemicals to a suitable volumetric flask.

5.1.4 Add sufficient purified water or other specified solvent to dissolve the chemicals completely.

5.1.5 Add purified water or other specified solvent to bring the solution to the final volume, ensuring the meniscus is at the calibration mark.

5.1.6 Mix the solution thoroughly to ensure homogeneity.

5.1.7 If required by the Dissolution Test Method, adjust the pH of the dissolution medium using a calibrated pH meter. Record the pH value in the Dissolution Test Apparatus Logbook (LOG-QC-007A).

5.1.8 Degas the dissolution medium using a degassing system (vacuum pump or helium sparging) to remove dissolved gases. This step is crucial to prevent air bubbles from interfering with the dissolution process.

5.1.9 Record the preparation date, lot number of chemicals used, pH (if adjusted), and degassing method in the Dissolution Test Apparatus Logbook (LOG-QC-007A).

5.2 Apparatus Setup

5.2.1 The QC Inspector verifies that the dissolution test apparatus is clean and in good working condition.

5.2.2 Select the appropriate apparatus type (Apparatus 1 – Basket, Apparatus 2 – Paddle, Apparatus 5 – Paddle over Disk) as specified in the Dissolution Test Method (STM-XXX).

5.2.3 Ensure that the dissolution vessels are clean, dry, and free from any scratches or cracks.

5.2.4 Carefully place the dissolution vessels into the water bath or heating system of the dissolution test apparatus.

5.2.5 Fill each vessel with the required volume of the prepared dissolution medium, as specified in the Dissolution Test Method (STM-XXX).

5.2.6 Ensure that all vessels contain the same volume of dissolution medium.

5.2.7 Place the appropriate stirring element (paddle or basket) onto the shaft and secure it tightly.

5.2.8 Lower the stirring element into the vessel, ensuring that it is centered and at the correct height above the bottom of the vessel, as specified in the Dissolution Test Method (STM-XXX). Generally, this distance is 25 ± 2 mm.

5.2.9 Turn on the water bath or heating system and allow the dissolution medium to equilibrate to the specified temperature (typically 37.0 ± 0.5 °C). Monitor the temperature using a calibrated temperature probe and record the temperature in the Dissolution Test Apparatus Logbook (LOG-QC-007A).

5.2.10 Verify that the stirring speed is set to the value specified in the Dissolution Test Method (STM-XXX).

5.3 Sample Introduction

5.3.1 Accurately weigh the required number of dosage units (tablets, capsules, etc.) as specified in the Dissolution Test Method (STM-XXX).

5.3.2 Record the weight of each dosage unit in the Dissolution Test Apparatus Logbook (LOG-QC-007A) or on a separate worksheet.

5.3.3 Carefully introduce one dosage unit into each dissolution vessel, ensuring that it is placed at the bottom of the vessel and does not stick to the sides.

5.3.4 Start the timer simultaneously with the addition of the dosage units.

5.3.5 Ensure the timer is accurate and traceable to a calibrated source.

5.4 Sampling

5.4.1 At the specified time points indicated in the Dissolution Test Method (STM-XXX), withdraw a sample from each dissolution vessel.

5.4.2 Use a calibrated pipette or an automated sampling system to withdraw the sample.

5.4.3 Ensure that the sampling probe is positioned at the specified location within the vessel, as described in the Dissolution Test Method (STM-XXX). Generally, this location is midway between the stirring element and the vessel wall, and midway between the surface of the dissolution medium and the top of the stirring element.

5.4.4 Filter the withdrawn sample immediately using a filter with the appropriate pore size (as specified in the Dissolution Test Method, STM-XXX) to remove any undissolved particles.

5.4.5 Transfer the filtered sample to a clean, labeled vial.

5.4.6 Replace the volume of dissolution medium withdrawn with an equal volume of fresh dissolution medium, pre-warmed to the specified temperature, to maintain a constant volume in the dissolution vessel (volume replacement).

5.4.7 Record the sampling time, volume withdrawn, and any observations in the Dissolution Test Apparatus Logbook (LOG-QC-007A).

5.5 Analysis

5.5.1 Analyze the collected samples using the analytical method specified in the Dissolution Test Method (STM-XXX). This may involve HPLC (HPC-01 or HPC-02), UV-Vis spectrophotometry (SPE-01 or SPE-02), or other appropriate techniques.

5.5.2 Ensure that the analytical instrument is calibrated and qualified prior to use.

5.5.3 Follow the established SOP for the operation of the analytical instrument.

5.5.4 Prepare standard solutions and quality control samples as specified in the Dissolution Test Method (STM-XXX).

5.5.5 Inject the samples, standards, and quality control samples into the analytical instrument.

5.5.6 Acquire and process the data using the instrument's software.

5.5.7 Calculate the amount of drug dissolved at each time point, based on the analytical results.

5.5.8 Record the analytical results and calculations in the Dissolution Test Apparatus Logbook (LOG-QC-007A) or on a separate worksheet.

5.6 Calibration

5.6.1 The dissolution test apparatus must be calibrated regularly, as specified in the calibration schedule.

5.6.2 The QC Inspector or designated personnel performs the calibration.

5.6.3 Calibration parameters include:

• Temperature: Verify the accuracy of the temperature control system using a calibrated temperature probe.

• Stirring Speed: Verify the accuracy of the stirring speed using a calibrated tachometer.

• Vessel Centering: Ensure that the vessels are properly centered in the water bath.

• Shaft Wobble: Check for excessive wobble of the stirring shafts.

• Verticality: Check the verticality of the shafts.

• Distance: Verify the distance between the bottom of the stirring element and the bottom of the vessel.

• Volume: Confirm the accurate volume of each vessel.

5.6.4 Document all calibration results in the Dissolution Test Apparatus Logbook (LOG-QC-007A).

5.6.5 If any calibration parameter is found to be out of specification, the QC Inspector immediately notifies the Production Supervisor and QA Manager.

5.6.6 The Production Supervisor and QA Manager investigate the out-of-specification condition and take appropriate corrective action.

5.6.7 The dissolution test apparatus is not used for testing until it has been recalibrated and verified to be within specifications.

5.7 Maintenance

5.7.1 Regular maintenance is essential to ensure the proper functioning and longevity of the dissolution test apparatus.

5.7.2 The QC Inspector performs routine maintenance tasks, such as:

- Cleaning the dissolution vessels and stirring elements after each use.
- Checking the water level in the water bath.
- Inspecting the stirring shafts for wear or damage.
- Lubricating moving parts as needed.

5.7.3 Preventative maintenance is performed by qualified service personnel according to the manufacturer's recommendations. This may include:

- Replacing worn parts.
- Adjusting the alignment of the stirring shafts.
- Cleaning the water bath and heating system.
- Checking the electrical connections.

5.7.4 Document all maintenance activities in the Dissolution Test Apparatus Logbook (LOG-QC-007A).

6.0 POST-ACTIVITY ACTIVITIES

6.1 After completion of the dissolution testing, the QC Inspector cleans all components of the dissolution test apparatus thoroughly.

6.2 The QC Inspector ensures that all dissolution vessels, paddles, baskets, and shafts are washed with a suitable detergent and rinsed with purified water.

6.3 All cleaned components are dried and stored in a designated area to prevent contamination.

6.4 The QC Inspector reviews the data generated during the dissolution testing to ensure accuracy and completeness.

6.5 The QC Inspector compares the dissolution results to the acceptance criteria specified in the Dissolution Test Method (STM-XXX).

6.6 If the dissolution results meet the acceptance criteria, the QC Inspector approves the results and forwards the data to the Production Supervisor and QA Manager for review.

6.7 If the dissolution results do not meet the acceptance criteria, the QC Inspector immediately notifies the Production Supervisor and QA Manager and initiates an Out-of-Specification (OOS) investigation.

6.8 The QA Manager reviews the OOS investigation report and determines the root cause of the OOS result.

6.9 The QA Manager implements corrective and preventative actions (CAPA) to prevent recurrence of the OOS result.

6.10 All records related to the dissolution testing, including the Dissolution Test Apparatus Logbook (LOG-QC-007A), Dissolution Test Method (STM-XXX), analytical results, and OOS investigation reports, are archived according to the document retention policy.

7.0 SAFETY PRECAUTIONS

7.1 Always wear safety glasses, a laboratory coat, and nitrile gloves when operating the dissolution test apparatus.

7.2 Handle chemicals and solvents with care, following the manufacturer's safety data sheets (SDS).

7.3 Avoid direct contact with hot surfaces of the water bath or heating system.

7.4 Do not operate the dissolution test apparatus if it is damaged or malfunctioning.

7.5 Ensure that the dissolution test apparatus is properly grounded to prevent electrical shock.

7.6 Dispose of used dissolution media and waste materials according to the established waste disposal procedures.

7.7 If any chemicals or solvents are spilled, clean them up immediately using appropriate absorbent materials.

7.8 If any equipment malfunctions or causes a safety hazard, immediately stop the testing and notify the Production Supervisor.

7.9 Work under a well-ventilated area, or use a fume hood when handling volatile solvents.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

Document Approval

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