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Title:	Analytical Method for Dissolution of Aspirin Tablets	Version:	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
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Analytical Method for Dissolution of Aspirin Tablets

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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Department: Quality Control Laboratory

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1.0 PURPOSE

This procedure defines the standardized analytical method for determining the dissolution rate of aspirin tablets in pharmaceutical manufacturing at NovaThera Pharmaceuticals, ensuring compliance with GMP and regulatory requirements. This SOP ensures the uniformity and consistency of dissolution testing across all applicable aspirin tablet products and batches.

2.0 SCOPE

This SOP applies to the Quality Control Laboratory at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India and covers the procedure for conducting dissolution testing of aspirin tablets, encompassing all relevant materials, equipment, and personnel involved in the analytical process. This procedure is applicable to all aspirin tablet products manufactured by NovaThera Pharmaceuticals, regardless of batch size or formulation variations within the approved specifications. The SOP excludes the dissolution testing of other drug products.

3.0 RESPONSIBILITY

QC Inspector: Responsible for performing the dissolution test according to this SOP, accurately recording all data, and ensuring the equipment is properly calibrated and maintained. The QC Inspector is also responsible for identifying and reporting any deviations from the procedure.

Production Supervisor: Responsible for ensuring that samples of aspirin tablets are properly collected and submitted to the Quality Control Laboratory for dissolution testing in a timely manner.

QA Manager: Responsible for reviewing and approving the dissolution testing data, ensuring that the test results meet the established acceptance criteria, and initiating investigations for any out-of-specification (OOS) results. The QA Manager is also responsible for the periodic review and revision of this SOP.

Head of QA: Responsible for the final approval of this SOP and any subsequent revisions, ensuring that the procedure is compliant with current GMP regulations and company policies.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, laboratory coat, nitrile gloves.

Equipment:

- Dissolution apparatus (e.g., USP Apparatus II, paddle method) with temperature control (e.g., DTG-05).
- UV-Vis Spectrophotometer (e.g., UVV-01) with suitable cuvettes.
- Analytical balance (e.g., BAL-02) with a readability of 0.1 mg.
- Calibrated thermometer (e.g., THR-03).
- Volumetric flasks and pipettes of appropriate sizes.
- Deionized water.
- Standard aspirin reference standard (e.g., SRS-ASP).
- Hydrochloric acid (HCl).
- Sodium hydroxide (NaOH).
- Filter paper (e.g., Whatman Grade 42).

Documentation:

- Dissolution Testing Record (Form QC-012-01).
- Equipment Calibration Logbook (Logbook EQ-001).
- Standard Operating Procedure (SOP-QC-012).
- UV-Vis Spectrophotometer Operation Manual (Manual UVV-01).

5.0 PROCEDURE

5.1 Preparation of Dissolution Medium

5.1.1 The QC Inspector verifies that the deionized water meets the in-house specifications for purity and conductivity.

5.1.2 The QC Inspector prepares the dissolution medium, which is 0.1 N hydrochloric acid (HCl). This involves diluting concentrated HCl with deionized water to achieve the desired concentration. The concentration is verified using a calibrated pH meter.

5.1.3 The QC Inspector records the preparation details, including the batch number of the HCl and the date of preparation, in the Dissolution Testing Record (Form QC-012-01).

5.1.4 The QC Inspector filters the dissolution medium through a 0.45 μm filter to remove any particulate matter.

5.2 Preparation of Aspirin Standard Solution

5.2.1 The QC Inspector retrieves the aspirin reference standard (SRS-ASP) from the controlled storage area.

5.2.2 The QC Inspector accurately weighs approximately 25 mg of the aspirin reference standard using the analytical balance (BAL-02) and records the exact weight in the Dissolution Testing Record (Form QC-012-01).

5.2.3 The QC Inspector transfers the weighed aspirin reference standard to a 100 mL volumetric flask.

5.2.4 The QC Inspector adds a sufficient amount of the dissolution medium (0.1 N HCl) to dissolve the aspirin.

5.2.5 The QC Inspector dilutes to the mark with the dissolution medium and mixes thoroughly to obtain a standard solution of approximately 250 µg/mL.

5.2.6 The QC Inspector calculates the exact concentration of the standard solution based on the weight of the aspirin reference standard used.

5.2.7 The QC Inspector prepares a series of dilutions from this stock solution to create a calibration curve for the UV-Vis Spectrophotometer.

5.3 Preparation of Samples

5.3.1 The Production Supervisor submits a representative sample of aspirin tablets from the batch to be tested to the Quality Control Laboratory.

5.3.2 The QC Inspector verifies the sample identity and records the batch number, date of receipt, and quantity of tablets received in the Dissolution Testing Record (Form QC-012-01).

5.3.3 The QC Inspector randomly selects six (6) tablets from the sample for dissolution testing.

5.4 Dissolution Testing Procedure

5.4.1 The QC Inspector ensures the dissolution apparatus (DTG-05) is clean and in proper working order.

5.4.2 The QC Inspector verifies the calibration status of the dissolution apparatus (DTG-05) by checking the Equipment Calibration Logbook (Logbook EQ-001).

5.4.3 The QC Inspector fills each of the six dissolution vessels with 900 mL of the prepared dissolution medium (0.1 N HCl).

5.4.4 The QC Inspector sets the temperature of the dissolution medium to $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ and allows the medium to equilibrate. The temperature is monitored using the calibrated thermometer (THR-03) and recorded in the Dissolution Testing Record (Form QC-012-01).

5.4.5 The QC Inspector sets the paddle speed to 50 rpm, as specified in the current USP monograph for Aspirin Delayed-Release Tablets.

5.4.6 The QC Inspector places one (1) aspirin tablet into each of the six dissolution vessels.

5.4.7 The QC Inspector starts the dissolution apparatus (DTG-05) and records the start time in the Dissolution Testing Record (Form QC-012-01).

5.4.8 The QC Inspector withdraws a 5 mL aliquot from each vessel at the specified time points (e.g., 5, 10, 15, 20, 30, and 45 minutes). The aliquots are withdrawn using a calibrated pipette.

5.4.9 The QC Inspector immediately filters the withdrawn aliquots through a $0.45\text{ }\mu\text{m}$ filter to remove any undissolved particles. The first 1-2 mL of the filtrate is discarded.

5.4.10 The QC Inspector collects the filtered samples in appropriately labeled vials.

5.5 Spectrophotometric Analysis

5.5.1 The QC Inspector ensures the UV-Vis Spectrophotometer (UVV-01) is clean, calibrated, and in proper working order.

5.5.2 The QC Inspector verifies the calibration status of the UV-Vis Spectrophotometer (UVV-01) by checking the Equipment Calibration Logbook (Logbook EQ-001).

5.5.3 The QC Inspector sets the UV-Vis Spectrophotometer (UVV-01) to the appropriate wavelength for aspirin detection (typically 265 nm).

5.5.4 The QC Inspector uses the prepared aspirin standard solution to create a calibration curve. The correlation coefficient of the calibration curve should be greater than 0.995.

5.5.5 The QC Inspector measures the absorbance of each filtered sample at 265 nm using the UV-Vis Spectrophotometer (UVV-01).

5.5.6 The QC Inspector records the absorbance values in the Dissolution Testing Record (Form QC-012-01).

5.5.7 The QC Inspector calculates the concentration of aspirin in each sample using the calibration curve.

5.5.8 The QC Inspector calculates the percentage of aspirin dissolved at each time point for each tablet.

5.6 Data Analysis and Acceptance Criteria

5.6.1 The QC Inspector calculates the average percentage of aspirin dissolved at each time point for the six tablets.

5.6.2 The QC Inspector calculates the standard deviation and relative standard deviation (RSD) for the percentage of aspirin dissolved at each time point.

5.6.3 The QC Inspector compares the results to the established acceptance criteria for aspirin dissolution, as specified in the current USP monograph for Aspirin Delayed-Release Tablets, which typically includes specifications at multiple time points to ensure proper drug release.

5.6.4 The QC Inspector documents the results of the data analysis and the comparison to the acceptance criteria in the Dissolution Testing Record (Form QC-012-01).

6.0 POST-DISSOLUTION TESTING ACTIVITIES

- 6.1 The QC Inspector cleans and stores all equipment used in the dissolution testing procedure.
- 6.2 The QC Inspector disposes of the dissolution medium and any remaining aspirin samples in accordance with the company's waste disposal procedures.
- 6.3 The QC Inspector reviews the Dissolution Testing Record (Form QC-012-01) for completeness and accuracy.
- 6.4 The QC Inspector submits the completed Dissolution Testing Record (Form QC-012-01) to the QA Manager for review and approval.
- 6.5 The QA Manager reviews the data and verifies that the results meet the established acceptance criteria.
- 6.6 If the results meet the acceptance criteria, the QA Manager approves the Dissolution Testing Record (Form QC-012-01) and releases the batch for further processing or distribution.
- 6.7 If the results do not meet the acceptance criteria (OOS), the QA Manager initiates an investigation to determine the cause of the failure and implements corrective and preventive actions (CAPA).

7.0 SAFETY PRECAUTIONS

- 7.1 All personnel involved in the dissolution testing procedure must wear appropriate personal protective equipment (PPE), including safety glasses, a laboratory coat, and nitrile gloves.
- 7.2 Handle hydrochloric acid (HCl) with care to avoid skin and eye contact. In case of contact, flush the affected area with copious amounts of water and seek medical attention.
- 7.3 Dispose of chemical waste in accordance with the company's waste disposal procedures.
- 7.4 Work in a well-ventilated area to avoid inhalation of vapors.
- 7.5 Be careful when handling glassware to avoid breakage and potential injuries.
- 7.6 Do not eat, drink, or smoke in the laboratory area.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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