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Title:	Operation, Calibration, and Maintenance of Analytical Balances	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Operation, Calibration, and Maintenance of Analytical Balances

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure defines the requirements for the proper operation, calibration, and maintenance of analytical balances within NovaThera Pharmaceuticals, ensuring accurate and reliable weighing of materials used in pharmaceutical manufacturing. This procedure ensures compliance with Good Manufacturing Practices (GMP) and regulatory requirements for data integrity and traceability.

2.0 SCOPE

This SOP applies to all analytical balances used within the NovaThera Pharmaceuticals Quality Control Laboratory and any other department where analytical balances are used for weighing materials, standards, or samples during the manufacturing, testing, and release of pharmaceutical products. This SOP covers all personnel responsible for operating, calibrating, and maintaining these balances, irrespective of the product or batch being analyzed. This procedure excludes balances used solely for non-critical, non-GMP related activities.

3.0 RESPONSIBILITY

QC Inspector:

- Operates analytical balances according to this SOP.
- Performs routine performance checks and documents results.
- Reports any malfunctions or deviations to the QA Manager.
- Ensures the balance is clean before and after use.
- Maintains accurate records of weighing activities.

Production Supervisor:

- Ensures that personnel are adequately trained on this SOP.
- Monitors adherence to this SOP by QC Inspectors.
- Provides necessary resources for the proper execution of this SOP.

QA Manager:

- Reviews and approves this SOP and any revisions.
- Oversees the calibration and maintenance schedule for analytical balances.
- Investigates any deviations or out-of-specification (OOS) results related to balance operation.
- Ensures compliance with GMP and regulatory requirements.
- Maintains training records related to this SOP.

Head of QA:

- Provides final approval for this SOP and any revisions.
- Ensures overall compliance with GMP and regulatory requirements related to analytical balance operation.
- Oversees the implementation of this SOP and its effectiveness.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Laboratory coat
- Gloves (nitrile or equivalent)

Equipment:

- Analytical Balance (e.g., Mettler Toledo XPE205, Sartorius Cubis MSA225S)
- Certified calibration weights (traceable to a national or international standard) - various denominations (e.g., 1 mg, 10 mg, 100 mg, 1 g, 10 g, 100 g, 200g)
- Anti-static brush
- Lint-free wipes
- Spatula or scoopula

- Weighing boats or paper

Documentation:

- Analytical Balance Usage Logbook (Form QC-008-01)
- Analytical Balance Calibration Record (Form QC-008-02)
- Analytical Balance Maintenance Log (Form QC-008-03)
- Deviation Report Form (QA-001)
- Training Record (HR-005)

5.0 PROCEDURE

5.1 Initial Setup and Preparation

5.1.1 The QC Inspector verifies that the analytical balance is located in a suitable environment, free from vibrations, drafts, and direct sunlight.

5.1.2 The QC Inspector ensures the balance is placed on a stable, level surface. Adjust the leveling feet if necessary, using the built-in level indicator on the balance, until the bubble is centered.

5.1.3 The QC Inspector cleans the balance weighing pan and surrounding area with a lint-free wipe and anti-static brush to remove any dust or residue.

5.1.4 The QC Inspector connects the balance to a stable power supply.

5.1.5 The QC Inspector turns on the balance and allows it to warm up for at least 30 minutes, as specified by the manufacturer's instructions.

5.1.6 The QC Inspector records the balance identification number, location, and date in the Analytical Balance Usage Logbook (Form QC-008-01).

5.2 Operation of the Analytical Balance

5.2.1 The QC Inspector ensures they are wearing appropriate PPE (safety glasses, laboratory coat, and gloves).

5.2.2 The QC Inspector verifies that the balance display shows “0.0000 g” (or the appropriate number of decimal places for the balance). If not, press the "Tare" button to zero the balance.

5.2.3 The QC Inspector places a weighing boat or paper on the balance pan.

5.2.4 The QC Inspector presses the "Tare" button again to zero the balance with the weighing boat or paper in place.

5.2.5 The QC Inspector carefully adds the substance to be weighed to the weighing boat or paper, using a spatula or scoopula. Avoid spilling material on the balance.

5.2.6 The QC Inspector allows the balance to stabilize until the weight reading is stable and the stability indicator on the display is activated.

5.2.7 The QC Inspector records the weight reading in the appropriate laboratory notebook or electronic system, along with the date, time, balance ID, and the analyst's initials.

5.2.8 The QC Inspector carefully removes the weighing boat or paper with the weighed substance.

5.2.9 The QC Inspector cleans the balance weighing pan and surrounding area with a lint-free wipe and anti-static brush to remove any residual material.

5.2.10 The QC Inspector records the completion of the weighing activity in the Analytical Balance Usage Logbook (Form QC-008-01).

5.3 Performance Check (Daily/Before Use)

5.3.1 The QC Inspector visually inspects the balance for any damage or abnormalities. If any damage is observed, the balance should not be used, and the QA Manager should be notified.

5.3.2 The QC Inspector ensures the balance is level using the built-in level indicator. Adjust the leveling feet if necessary.

5.3.3 The QC Inspector cleans the balance weighing pan and surrounding area.

5.3.4 The QC Inspector performs a zero test by ensuring the balance reads "0.0000 g" (or appropriate decimal places) when the pan is empty. Tare if needed.

5.3.5 The QC Inspector selects a calibrated weight close to the typical weight range used in the analysis. For example, if the usual weights are around 10g, a 10g calibrated weight should be used.

5.3.6 The QC Inspector carefully places the calibrated weight on the center of the weighing pan.

5.3.7 The QC Inspector records the weight displayed by the balance.

5.3.8 The QC Inspector compares the displayed weight to the certified value of the calibrated weight. The difference should be within the acceptable tolerance (e.g., ±0.1 mg for a balance with 0.01 mg readability). This tolerance should be defined based on the balance manufacturer's specifications and the criticality of the measurement.

5.3.9 The QC Inspector removes the calibrated weight.

5.3.10 The QC Inspector repeats steps 5.3.6-5.3.9 two more times, for a total of three readings.

5.3.11 The QC Inspector calculates the average of the three readings.

5.3.12 The QC Inspector records the date, balance ID, weight used, individual readings, average reading, and the acceptable tolerance range in the Analytical Balance Calibration Record (Form QC-008-02) under the "Daily Performance Check" section. The QC Inspector should also initial and date the record.

5.3.13 If the average reading is outside the acceptable tolerance range, the QC Inspector immediately stops using the balance, notifies the QA Manager, and affixes a "Do Not Use" label to the balance. A deviation should be initiated.

5.3.14 The QA Manager will investigate the deviation and determine the appropriate corrective action, which may include recalibration of the balance by a qualified service technician.

5.4 Calibration (Periodic - e.g., Weekly/Monthly)

5.4.1 The QA Manager determines the calibration frequency based on the balance usage, risk assessment, and regulatory requirements. The frequency should be documented in a master calibration schedule.

5.4.2 The QC Inspector (or designated qualified personnel) performs the calibration using certified calibration weights traceable to a national or international standard.

5.4.3 The QC Inspector ensures the balance is clean and level before starting the calibration.

5.4.4 The QC Inspector follows the balance manufacturer's instructions for calibration. This typically involves using multiple calibration weights spanning the balance's weighing range (e.g., low, mid, and high range).

5.4.5 The QC Inspector records all calibration data, including the date, balance ID, weights used, displayed values, and any adjustments made, in the Analytical Balance Calibration Record (Form QC-008-02).

5.4.6 The QC Inspector evaluates the calibration results against pre-defined acceptance criteria. These criteria should be based on the balance manufacturer's specifications and the requirements of the specific application.

5.4.7 If the calibration results are within the acceptance criteria, the QC Inspector signs and dates the calibration record, indicating successful completion.

5.4.8 If the calibration results are outside the acceptance criteria, the QC Inspector immediately stops using the balance, notifies the QA Manager, and affixes a "Do Not Use" label to the balance. A deviation should be initiated.

5.4.9 The QA Manager will investigate the deviation and determine the appropriate corrective action, which may include recalibration of the balance by a qualified service technician or repair of the balance.

5.4.10 After successful calibration, the QA Manager updates the calibration status of the balance in the calibration management system.

5.5 Maintenance

5.5.1 The QC Inspector performs routine cleaning of the balance after each use, as described in Section 5.2.9.

5.5.2 The QC Inspector periodically (e.g., monthly) performs a more thorough cleaning of the balance, including the weighing pan, draft shield (if applicable), and surrounding area. Use a lint-free wipe and a mild cleaning solution, if necessary.

5.5.3 The QC Inspector records all maintenance activities in the Analytical Balance Maintenance Log (Form QC-008-03), including the date, description of the maintenance performed, and the initials of the person performing the maintenance.

5.5.4 The QA Manager schedules preventative maintenance by a qualified service technician, as recommended by the balance manufacturer. This may include internal adjustments, cleaning, and lubrication. The frequency of preventative maintenance should be based on the balance usage, risk assessment, and the manufacturer's recommendations.

5.5.5 The QC Inspector ensures that any repairs or replacements are performed by qualified personnel and are documented in the Analytical Balance Maintenance Log (Form QC-008-03).

6.0 POST-ACTIVITY ACTIVITIES

6.1 After completing the weighing activity, the QC Inspector ensures the balance is clean and ready for the next user.

6.2 The QC Inspector ensures that all data is accurately recorded in the appropriate laboratory notebook or electronic system.

6.3 The QC Inspector returns all calibration weights to their designated storage location.

6.4 The QC Inspector reviews the Analytical Balance Usage Logbook (Form QC-008-01) and Analytical Balance Calibration Record (Form QC-008-02) to ensure completeness and accuracy.

6.5 The QC Inspector notifies the QA Manager of any deviations or anomalies observed during the procedure.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE (safety glasses, laboratory coat, and gloves) when operating and maintaining the analytical balance.

7.2 Avoid spilling materials on the balance. If a spill occurs, immediately clean it up using appropriate cleaning agents and dispose of the waste properly.

7.3 Do not exceed the maximum weighing capacity of the balance.

7.4 Do not attempt to repair the balance yourself. Contact a qualified service technician for any repairs or maintenance beyond routine cleaning.

7.5 Use caution when handling calibration weights to avoid dropping them or causing damage.

7.6 Be aware of potential electrostatic discharge (ESD) when weighing materials. Use an anti-static brush or other appropriate measures to minimize the risk of ESD.

7.7 If using flammable or hazardous materials, ensure proper ventilation and follow all relevant safety procedures.

7.8 Dispose of any waste materials (e.g., used wipes, weighing paper) in accordance with established waste disposal procedures.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Controlled Document Notice

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
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