Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-ENG-002
Title:	Calibration Program for Instruments and Gauges	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Calibration Program for Instruments and Gauges

Category: Engineering & Maintenance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Engineering & Maintenance

Title: Calibration Program for Instruments and Gauges

SOP No.: SOP-ENG-002

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

This procedure defines the requirements and steps for the calibration of instruments and gauges used in pharmaceutical manufacturing at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures that all instruments and gauges used in manufacturing, testing, and monitoring processes are accurately calibrated and maintained to meet Good Manufacturing Practices (GMP) and regulatory requirements, ensuring data integrity and product quality.

2.0 SCOPE

This SOP applies to all instruments and gauges used in pharmaceutical manufacturing, quality control, and research and development at NovaThera Pharmaceuticals Pvt. Ltd., including but not limited to: balances, pH meters, thermometers, pressure gauges, flow meters, analytical equipment (e.g., HPLC, GC), blenders (BLN-04), tablet presses (TCP-01), sifters (SFT-02), and other measuring devices used in the production and testing of pharmaceutical materials and products. This procedure covers all stages of the instrument lifecycle, from initial installation to decommissioning. It is applicable to all products manufactured, tested, or stored at the NovaThera Pharmaceuticals facility.

3.0 RESPONSIBILITY

QC Inspector:

- Performs calibration checks on instruments and gauges according to the established schedule.
- Documents calibration results accurately and completely in the appropriate logbooks and forms.
- Reports any out-of-tolerance conditions or instrument malfunctions to the Production Supervisor and QA Manager.
- Affixes calibration labels to instruments and gauges indicating the calibration date and due date.
- Maintains calibration standards and reference materials in accordance with established procedures.
- Assists in troubleshooting instrument problems.

Production Supervisor:

- Ensures that all instruments and gauges used in production processes are calibrated and in good working order.
- Coordinates calibration activities with the QC Inspector and QA Manager.
- Notifies the QA Manager of any instrument malfunctions or out-of-tolerance conditions.
- Ensures that operators are trained on the proper use and handling of calibrated instruments.
- Reviews calibration records and verifies that all required calibrations have been performed.
- Participates in investigations of instrument-related deviations.

QA Manager:

- Develops and maintains the calibration program for all instruments and gauges.
- Reviews and approves calibration procedures and schedules.
- Ensures that calibration standards are traceable to national or international standards.
- Investigates instrument-related deviations and implements corrective and preventive actions (CAPA).
- Oversees the training of personnel on calibration procedures.
- Approves calibration records and reports.
- Conducts periodic audits of the calibration program.

Head of QA:

- Provides overall oversight of the calibration program.
- Approves changes to the calibration program.
- Ensures that the calibration program is compliant with GMP regulations and company policies.
- Resolves any disputes related to calibration activities.
- Provides resources necessary for the effective implementation of the calibration program.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or latex, as appropriate for the specific task and materials being handled)
- Lab coat

Equipment:

- Calibration standards (traceable to national or international standards)
- Standard weights (for balances)
- Certified thermometers
- Pressure calibrators
- Flow calibrators
- pH buffers
- Multimeter
- Tachometer
- Voltmeter
- Ammeter
- Stopwatches
- Digital calipers
- Instrument-specific calibration tools and kits (e.g., for HPLC, GC)
- Computer with calibration software (if applicable)
- Calibrated reference instruments

Documentation:

- Instrument Calibration Logbook (Form No. QA-CAL-001)
- Instrument Calibration Record (Form No. QA-CAL-002)
- Calibration Schedule (Form No. ENG-SCH-001)
- Out-of-Tolerance Report (Form No. QA-OOT-001)
- Deviation Report (Form No. QA-DEV-001)
- Corrective and Preventive Action (CAPA) Form (Form No. QA-CAPA-001)
- Instrument History File (maintained electronically or in hard copy)
- SOP-ENG-002 Calibration Program for Instruments and Gauges
- Equipment User Manuals

5.0 PROCEDURE

5.1 Calibration Schedule Development and Maintenance

5.1.1 The QA Manager shall develop and maintain a master calibration schedule (Form No. ENG-SCH-001) that includes all instruments and gauges requiring calibration.

5.1.2 The calibration schedule shall specify the instrument name, location, identification number, calibration frequency, calibration method, and calibration acceptance criteria.

5.1.3 The calibration frequency shall be determined based on the instrument manufacturer's recommendations, regulatory requirements, risk assessment, historical data, and the criticality of the instrument to product quality.

5.1.4 The QA Manager shall review the calibration schedule at least annually and update it as needed.

5.1.5 Any changes to the calibration schedule shall be documented and approved by the Head of QA.

5.1.6 The QC Inspector will receive a monthly reminder to conduct calibration due in that month.

5.2 Instrument Identification and Labeling

5.2.1 All instruments and gauges shall be clearly identified with a unique identification number.

5.2.2 Each instrument shall be labeled with a calibration sticker indicating the date of calibration, the date of the next calibration, and the initials of the person who performed the calibration.

5.2.3 The calibration sticker shall be placed in a conspicuous location on the instrument.

5.2.4 The QC Inspector is responsible for ensuring that all instruments are properly labeled.

5.2.5 Instruments without a valid calibration sticker shall not be used.

5.3 Calibration Procedure

5.3.1 The QC Inspector shall perform calibration checks on instruments and gauges according to the calibration schedule and the applicable calibration procedure.

5.3.2 Prior to performing calibration, the QC Inspector shall verify that the instrument is clean and in good working order.

5.3.3 The QC Inspector shall use calibration standards that are traceable to national or international standards.

5.3.4 The calibration procedure shall include the following steps:

- Verify the instrument identification and location.
- Record the instrument's ambient conditions (temperature, humidity).
- Visually inspect the instrument for any damage or defects.
- Perform a zero adjustment (if applicable).
- Apply known calibration standards to the instrument.
- Record the instrument's readings for each calibration standard.
- Compare the instrument's readings to the known values of the calibration standards.
- Determine if the instrument's readings are within the acceptable tolerance limits.
- Adjust the instrument (if necessary) to bring its readings within the acceptable tolerance limits.
- Document the calibration results in the Instrument Calibration Record (Form No. QA-CAL-002).
- Affix a calibration sticker to the instrument indicating the date of calibration, the date of the next calibration, and the initials of the person who performed the calibration.

5.3.5 Specific Calibration Examples:

• Balances: Calibration will be performed using certified weights, following the manufacturer's instructions. Linearity, repeatability and accuracy must be within acceptable limits as per the instrument specification.

• pH Meters: Calibrate using at least two pH buffer solutions (e.g., pH 4.0, pH 7.0, and pH 10.0) that are traceable to NIST standards. Slope and offset must be within acceptance criteria.

• Thermometers: Compare the reading to a calibrated reference thermometer in a controlled temperature bath.

• Pressure Gauges: Use a pressure calibrator to apply known pressures and compare the gauge reading.

• HPLC/GC: Calibration should include multiple concentration levels of standard solutions. Evaluate linearity, accuracy, and precision.

5.3.6 If the instrument is found to be out of tolerance, the QC Inspector shall notify the Production Supervisor and QA Manager immediately.

5.3.7 The QA Manager shall investigate the out-of-tolerance condition and determine the potential impact on product quality.

5.3.8 The QC Inspector shall perform necessary adjustments, repairs, or replacement as directed by the QA Manager.

5.4 Documentation of Calibration Results

5.4.1 The QC Inspector shall document all calibration results in the Instrument Calibration Record (Form No. QA-CAL-002).

5.4.2 The Instrument Calibration Record shall include the following information:

• Instrument name and identification number

• Calibration date

• Calibration standard used

• Calibration results (readings)

• Acceptance criteria

• Calibration status (pass/fail)

• Name and signature of the person who performed the calibration
• Date of next calibration

5.4.3 The Instrument Calibration Record shall be reviewed and approved by the QA Manager.

5.4.4 The Instrument Calibration Records shall be maintained in the Instrument Calibration Logbook (Form No. QA-CAL-001) and in the Instrument History File.

5.5 Out-of-Tolerance (OOT) Investigations

5.5.1 Any instrument or gauge found to be out of tolerance during calibration or use shall be immediately removed from service.

5.5.2 The QC Inspector shall complete an Out-of-Tolerance Report (Form No. QA-OOT-001) documenting the following information:

• Instrument name and identification number
• Date and time the OOT condition was discovered
• Description of the OOT condition
• Potential impact on product quality
• Corrective action taken

5.5.3 The QA Manager shall investigate the OOT condition and determine the root cause.

5.5.4 The QA Manager shall implement corrective and preventive actions (CAPA) to prevent recurrence of the OOT condition.

5.5.5 All OOT investigations shall be documented in the Instrument History File.

5.6 Corrective and Preventive Action (CAPA)

5.6.1 If an OOT condition or instrument malfunction is determined to be the result of a systemic problem, the QA Manager shall initiate a CAPA (Form No. QA-CAPA-001).

5.6.2 The CAPA shall include the following elements:

- Problem statement
- Root cause analysis
- Corrective action(s)
- Preventive action(s)
- Verification of effectiveness
- Implementation timeline
- Responsibility

5.6.3 The Head of QA shall approve the CAPA.

5.6.4 The QA Manager shall monitor the implementation of the CAPA and verify its effectiveness.

5.6.5 All CAPAs shall be documented in the CAPA file and in the Instrument History File.

5.7 Instrument Maintenance

5.7.1 Routine maintenance shall be performed on all instruments and gauges according to the manufacturer's recommendations.

5.7.2 The Production Supervisor is responsible for ensuring that routine maintenance is performed.

5.7.3 Maintenance activities shall be documented in the Instrument History File.

5.7.4 Any repairs or modifications to instruments shall be performed by qualified personnel.

5.7.5 After any repair or modification, the instrument shall be recalibrated before being returned to service.

5.8 Decommissioning of Instruments

5.8.1 When an instrument or gauge is no longer needed or is being replaced, it shall be properly decommissioned.

5.8.2 The Production Supervisor shall notify the QA Manager of the decommissioning.

5.8.3 The QA Manager shall remove the instrument from the calibration schedule.

5.8.4 The Instrument History File shall be updated to reflect the decommissioning.

5.8.5 The instrument shall be disposed of in accordance with company procedures and applicable regulations.

6.0 POST-CALIBRATION ACTIVITIES

6.1 Following calibration, the QC Inspector shall ensure the instrument is returned to its designated location.

6.2 The QC Inspector will update the calibration logbook and the electronic maintenance system with the calibration results.

6.3 The QC Inspector will immediately notify the Production Supervisor if any instrument is not returned to service.

6.4 The QA Manager shall periodically review calibration records and trends to identify potential improvements to the calibration program.

6.5 All records related to calibration shall be stored securely in accordance with company record retention policies.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE (safety glasses, gloves, lab coat) when performing calibration activities.

7.2 Follow the manufacturer's instructions for the safe use of calibration standards and equipment.

7.3 Use caution when handling electrical equipment to avoid electrical shock.

7.4 Ensure that work areas are clean and well-lit.

7.5 Report any accidents or injuries to the Production Supervisor immediately.

7.6 Use appropriate lifting techniques when handling heavy equipment or calibration standards.

7.7 Be aware of potential hazards associated with the materials being measured (e.g., corrosive chemicals, flammable solvents) and take appropriate precautions.

7.8 Ensure proper ventilation when working with volatile substances.

7.9 Disconnect equipment from power sources before performing any maintenance or repairs.

7.10 Properly dispose of used calibration standards and waste materials in accordance with company procedures and applicable regulations.

8.0 APPROVALS

Prepared By: Engineering Department

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
Reviewed by (QA):	_____	_____	_____
Approved by (Head QA):	_____	_____	_____

Document Control Information

Document ID: SOP-ENG-002

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System