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Operation, Calibration, and Maintenance of the IR Spectrometer

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines the procedure for the proper operation, calibration, and maintenance of the Infrared (IR) Spectrometer (Model: IRS-1000) in the Quality Control Laboratory at NovaThera Pharmaceuticals Pvt. Ltd. This procedure ensures the instrument's accuracy, reliability, and suitability for its intended use in pharmaceutical manufacturing. Adherence to this SOP ensures compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines.

2.0 SCOPE

This SOP applies to all Quality Control personnel involved in the operation, calibration, and maintenance of the Infrared (IR) Spectrometer (Model: IRS-1000) used for the identification and qualitative analysis of raw materials, in-process samples, and finished products at NovaThera Pharmaceuticals Pvt. Ltd. This procedure covers all applicable products and batches tested using the IR Spectrometer. This SOP excludes the advanced troubleshooting and repair of the instrument, which should be performed by qualified service engineers.

3.0 RESPONSIBILITY

QC Inspector:

- Operates the IR Spectrometer according to this SOP.
- Performs routine performance checks and calibration verification of the IR Spectrometer.
- Records all operational data, calibration results, and maintenance activities in the instrument's logbook (Form: QCL-006-01).
- Reports any deviations, malfunctions, or out-of-specification results to the QA Manager immediately.
- Ensures the cleanliness and proper storage of the IR Spectrometer and its accessories.

QA Manager:

- Reviews and approves the instrument's logbook entries and calibration records.
- Investigates any deviations or out-of-specification results reported by the QC Inspector.
- Ensures that the IR Spectrometer is calibrated according to the established schedule.
- Arranges for preventative maintenance and repairs of the IR Spectrometer as needed.
- Updates and revises this SOP as necessary.

Head of QA:

- Provides overall oversight of the Quality Control Laboratory operations.
- Approves the calibration schedule and any deviations from this SOP.
- Ensures that all QC personnel are adequately trained on this SOP.
- Periodically audits the implementation of this SOP to ensure compliance.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or latex)
- Lab coat

Equipment:

- Infrared (IR) Spectrometer (Model: IRS-1000)
- Computer with IR Spectrometer software (Version 5.2)
- Sample preparation accessories (e.g., mortar and pestle, KBr press, liquid cells)
- Potassium Bromide (KBr), IR grade
- Reference standards (traceable to a recognized pharmacopeia)
- Cleaning solutions (e.g., Isopropyl Alcohol, distilled water)
- Lint-free wipes
- Desiccator

- Spatula
- Analytical balance (Model: BAL-003)

Documentation:

- IR Spectrometer Logbook (Form: QCL-006-01)
- IR Spectrometer Calibration Record (Form: QCL-006-02)
- Equipment Usage Log (Form GEN-004)
- Deviation Report Form (Form QA-001)

5.0 PROCEDURE

5.1 Instrument Preparation

5.1.1 Ensure the IR Spectrometer is located in a clean and stable environment, free from excessive vibration, dust, and humidity.

5.1.2 Verify that the power cord is securely connected to the instrument and the power outlet.

5.1.3 Turn on the IR Spectrometer and the computer.

5.1.4 Allow the IR Spectrometer to warm up for at least 30 minutes before use, as per the manufacturer's recommendations.

5.1.5 Launch the IR Spectrometer software on the computer.

5.1.6 Check the instrument status in the software to ensure that all components are functioning correctly.

5.1.7 If any error messages or unusual readings are observed, notify the QA Manager immediately.

5.1.8 Document the instrument start-up in the Equipment Usage Log (Form GEN-004).

5.2 Sample Preparation

5.2.1 Select the appropriate sample preparation method based on the nature of the sample (e.g., solid, liquid, or gas) and the analytical requirements.

5.2.2 For solid samples:

5.2.2.1 Grind a small amount of the sample into a fine powder using a mortar and pestle.

5.2.2.2 Mix the powdered sample with IR grade KBr in a ratio of approximately 1:100 (sample: KBr).

5.2.2.3 Accurately weigh the sample and KBr using the analytical balance (Model: BAL-003) and record the weights in the instrument's logbook.

5.2.2.4 Thoroughly mix the sample and KBr using the mortar and pestle.

5.2.2.5 Prepare a KBr disc using a KBr press according to the manufacturer's instructions. Ensure the disc is clear and free from cracks or imperfections.

5.2.3 For liquid samples:

5.2.3.1 Place a small amount of the liquid sample into a suitable liquid cell.

5.2.3.2 Ensure the cell windows are clean and free from any contaminants.

5.2.3.3 Securely close the liquid cell and position it in the IR Spectrometer sample holder.

5.2.4 For gas samples:

5.2.4.1 Fill a suitable gas cell with the gas sample.

5.2.4.2 Ensure the cell windows are clean and free from any contaminants.

5.2.4.3 Securely close the gas cell and position it in the IR Spectrometer sample holder.

5.2.5 Handle all samples with care to avoid contamination.

5.2.6 Document the sample preparation method used in the instrument's logbook.

5.3 Instrument Operation

5.3.1 Ensure the IR Spectrometer is properly configured according to the sample type and analytical requirements.

5.3.2 Select the appropriate scan parameters in the software, such as resolution, scan range, and number of scans. The recommended scan range is 4000 cm-1 to 400 cm-1 with a resolution of 4 cm-1.

5.3.3 Record the scan parameters in the instrument's logbook.

5.3.4 Run a background scan using a blank KBr disc (for solid samples) or an empty liquid cell (for liquid samples) to compensate for any background interference.

5.3.5 Place the sample in the IR Spectrometer sample holder.

5.3.6 Start the scan using the software.

5.3.7 Monitor the scan progress and ensure that the spectrum is being acquired correctly.

5.3.8 Once the scan is complete, save the spectrum to a designated folder on the computer with a unique filename that includes the sample name, date, and analyst initials.

5.3.9 Print a copy of the spectrum for record-keeping purposes.

5.3.10 Remove the sample from the IR Spectrometer and clean the sample holder.

5.3.11 Document the instrument operation in the instrument's logbook, including the sample name, date, time, analyst initials, and any relevant observations.

5.4 Data Analysis

5.4.1 Compare the obtained spectrum to a reference spectrum of the known standard (traceable to a recognized pharmacopeia) or the material specification.

5.4.2 Identify the characteristic peaks and compare their positions and intensities to those in the reference spectrum.

5.4.3 Use the software's search function to identify the sample based on its spectrum.

5.4.4 Document the results of the data analysis in the instrument's logbook.

5.4.5 If the spectrum matches the reference spectrum and meets the acceptance criteria, record the result as "Pass."

5.4.6 If the spectrum does not match the reference spectrum or does not meet the acceptance criteria, record the result as "Fail" and initiate a Deviation Report (Form QA-001).

5.5 Calibration

5.5.1 The IR Spectrometer should be calibrated at least once every six months or more frequently if required, as determined by the QA Manager.

5.5.2 The calibration procedure should be performed using certified reference materials (traceable to a recognized pharmacopeia) that cover the entire spectral range.

5.5.3 Prepare the reference materials according to the manufacturer's instructions.

5.5.4 Run a scan of each reference material and compare the obtained spectrum to the certified spectrum.

5.5.5 Verify that the peak positions and intensities are within the acceptable tolerance limits specified by the manufacturer and the relevant pharmacopeia.

5.5.6 Record the calibration results in the IR Spectrometer Calibration Record (Form: QCL-006-02).

5.5.7 If the calibration results are within the acceptable limits, affix a calibration sticker to the instrument indicating the date of calibration and the date of the next calibration.

5.5.8 If the calibration results are not within the acceptable limits, perform corrective action, such as adjusting the instrument parameters or replacing faulty components.

5.5.9 After performing corrective action, repeat the calibration procedure to verify that the instrument is now calibrated.

5.5.10 If the instrument cannot be calibrated, remove it from service and notify the QA Manager.

5.6 Maintenance

5.6.1 Perform routine maintenance of the IR Spectrometer according to the manufacturer's instructions.

5.6.2 Clean the instrument regularly using a soft, lint-free cloth and a mild cleaning solution (e.g., Isopropyl Alcohol).

5.6.3 Clean the sample holder after each use to prevent contamination.

5.6.4 Check the instrument's desiccant regularly and replace it as needed.

5.6.5 Perform preventative maintenance, such as replacing the source lamp, as recommended by the manufacturer.

5.6.6 Record all maintenance activities in the instrument's logbook.

5.6.7 If any repairs are required, contact a qualified service engineer to perform the repairs.

5.6.8 After repairs, verify that the instrument is functioning correctly by performing a calibration check.

6.0 POST-ANALYSIS ACTIVITIES

6.1 Clean the sample holder and any other accessories used during the analysis.

6.2 Properly dispose of any used samples and reagents according to established waste disposal procedures.

6.3 Turn off the IR Spectrometer and the computer.

6.4 Cover the IR Spectrometer with a dust cover to protect it from dust and other contaminants.

6.5 Store all samples and reference materials in a secure and properly labeled location.

6.6 Review the instrument's logbook to ensure that all entries are complete and accurate.

6.7 File the printed spectra and calibration records in a designated location.

6.8 Update the Equipment Usage Log (Form GEN-004) with the completion time.

7.0 SAFETY PRECAUTIONS

7.1 Wear appropriate PPE, including safety glasses, gloves, and a lab coat, when operating the IR Spectrometer.

7.2 Handle KBr with care to avoid skin and eye contact.

7.3 Avoid inhaling KBr dust.

7.4 Use caution when handling liquid samples, especially if they are flammable or corrosive.

7.5 Do not operate the IR Spectrometer if it is damaged or malfunctioning.

7.6 Ensure that the instrument is properly grounded to prevent electrical shock.

7.7 Follow all safety guidelines and procedures established by NovaThera Pharmaceuticals Pvt. Ltd.

7.8 In case of any chemical spills, refer to the relevant Material Safety Data Sheet (MSDS) and follow the appropriate cleanup procedures.

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

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

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