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Title:	Handling of Laboratory Reagents and Reference Standards	**Version:**	1.0
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Handling of Laboratory Reagents and Reference Standards

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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Department: Quality Control

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1.0 PURPOSE

This procedure defines the requirements for the receipt, storage, handling, use, and disposal of laboratory reagents and reference standards within NovaThera Pharmaceuticals' quality control laboratory to ensure data integrity, accurate and reliable analytical results, and compliance with Good Manufacturing Practices (GMP). This procedure also outlines the process for maintaining proper documentation and traceability of reagents and reference standards used in pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all personnel involved in the receipt, storage, handling, use, and disposal of laboratory reagents and reference standards used for testing raw materials, in-process samples, finished products, and stability samples at NovaThera Pharmaceuticals. This includes all reagents and reference standards used in the Quality Control Laboratory, irrespective of the manufacturer or supplier, and is applicable to all pharmaceutical products manufactured at NovaThera Pharmaceuticals Pvt. Ltd.

3.0 RESPONSIBILITY

QC Inspector: Responsible for receiving, inspecting, logging, storing, preparing, using, and disposing of reagents and reference standards according to this SOP. Responsible for maintaining accurate records and ensuring compliance with all applicable procedures and regulations.

Production Supervisor: Responsible for ensuring that all personnel involved in the use of reagents and reference standards are trained on this SOP.

QA Manager: Responsible for reviewing and approving this SOP and any associated documentation. Responsible for ensuring that the Quality Control Laboratory is in compliance with GMP requirements related to the handling of reagents and reference standards. Responsible for oversight of the reagent and reference standard management program.

Head of QA: Responsible for the final approval of this SOP. Responsible for ensuring the overall quality system is maintained and meets regulatory requirements.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, laboratory coat, chemical-resistant gloves (nitrile), face mask (as needed).

Equipment: Refrigerator (maintained at 2-8°C), Freezer (maintained at -20°C), Chemical Storage Cabinets, calibrated balances (BAL-01, BAL-02), Volumetric flasks, Pipettes, Desiccator, pH meter (PHM-01), Stirrer (STR-01).

Documentation: Reagent Log Book (RLB-01), Reference Standard Log Book (RSLB-01), Material Safety Data Sheets (MSDS), Certificates of Analysis (CoA), Reagent Labels, Reference Standard Labels, Discrepancy Report Form (DRF-01), Temperature Monitoring Log (TML-01).

5.0 PROCEDURE

5.1 Receipt and Inspection of Reagents and Reference Standards

5.1.1 Upon receipt of a reagent or reference standard shipment, the QC Inspector shall verify the integrity of the package and ensure that it is free from damage.

5.1.2 The QC Inspector shall compare the information on the shipping manifest with the purchase order and the actual contents of the shipment. Any discrepancies shall be reported to the QA Manager and documented on a Discrepancy Report Form (DRF-01).

5.1.3 The QC Inspector shall verify that the reagent or reference standard has been received before the expiration date provided by the supplier.

5.1.4 The QC Inspector shall visually inspect the reagent or reference standard container for any signs of damage, leakage, or contamination. Any damaged or compromised containers shall be quarantined and reported to the QA Manager and documented on a Discrepancy Report Form (DRF-01).

5.1.5 The QC Inspector shall obtain the Material Safety Data Sheet (MSDS) for each reagent and make it readily accessible to all laboratory personnel.

5.1.6 For Reference Standards: The QC Inspector shall verify the identity and purity of the reference standard against its Certificate of Analysis (CoA).

5.1.7 The QC Inspector shall assign a unique, sequential internal control number to each received reagent or reference standard. The format should be NT-Reagent/RS-YYMM-### (where YY is the year, MM is the month, and ### is the sequential number).

5.1.8 The QC Inspector shall log all received reagents and reference standards into the appropriate log book (Reagent Log Book (RLB-01) or Reference Standard Log Book (RSLB-01)). The log book entry shall include the following information:

- Date of Receipt
- Reagent/Reference Standard Name
- Supplier Name
- Supplier Lot Number
- Expiration Date
- Quantity Received
- Internal Control Number
- Initial Inspection Results
- Name and Signature of QC Inspector

5.1.9 The QC Inspector shall affix a label to each reagent or reference standard container with the following information:

- Reagent/Reference Standard Name
- Internal Control Number
- Receipt Date
- Expiration Date
- Storage Conditions
- Hazard Warnings (as per MSDS)

5.2 Storage of Reagents and Reference Standards

5.2.1 The QC Inspector shall store all reagents and reference standards according to the manufacturer's recommended storage conditions, as specified on the product label and MSDS/CoA.

5.2.2 Reagents and reference standards requiring refrigerated storage shall be stored in the refrigerator (maintained at 2-8°C). The temperature of the refrigerator shall be monitored daily using the Temperature Monitoring Log (TML-01). Any excursions outside the acceptable temperature range shall be investigated and documented.

5.2.3 Reagents and reference standards requiring freezer storage shall be stored in the freezer (maintained at -20°C). The temperature of the freezer shall be monitored daily using the Temperature Monitoring Log (TML-01). Any excursions outside the acceptable temperature range shall be investigated and documented.

5.2.4 Flammable reagents shall be stored in designated flammable storage cabinets in accordance with applicable safety regulations.

5.2.5 Light-sensitive reagents shall be stored in amber-colored containers or protected from light by other appropriate means.

5.2.6 All reagents and reference standards shall be stored in a manner that prevents contamination and degradation.

5.2.7 Expired reagents and reference standards shall be clearly labeled as "EXPIRED" and segregated from in-date materials.

5.2.8 The QC Inspector shall perform a periodic inventory of all reagents and reference standards to ensure that stock levels are adequate and that expired materials are removed.

5.2.9 The storage areas should be clean, organized, and properly ventilated.

5.3 Handling and Use of Reagents and Reference Standards

5.3.1 Prior to using any reagent or reference standard, the QC Inspector shall verify the following:

- The reagent/reference standard is within its expiration date.
- The reagent/reference standard has been stored according to the manufacturer's recommendations.
- The reagent/reference standard container is intact and free from damage or contamination.
- The reagent/reference standard is appropriate for the intended use.

5.3.2 The QC Inspector shall wear appropriate PPE, as specified in Section 4.0, when handling reagents and reference standards.

5.3.3 Reagents and reference standards shall be handled in a manner that prevents contamination. Use appropriate techniques, such as using clean glassware and pipettes, and avoiding contact with skin or other surfaces.

5.3.4 Only the amount of reagent or reference standard needed for the analysis should be removed from the container.

5.3.5 The QC Inspector shall accurately weigh or measure the required amount of reagent or reference standard using calibrated balances (BAL-01, BAL-02) and volumetric flasks/pipettes.

5.3.6 All weighing and measuring activities shall be documented in the appropriate laboratory notebook or worksheet.

5.3.7 If a reagent or reference standard requires dilution or preparation, the procedure shall be performed according to the validated method and documented in the laboratory notebook or worksheet.

5.3.8 Used reagents and reference standards shall be disposed of properly, as described in Section 5.4.

5.3.9 After use, the QC Inspector shall ensure the original container is properly closed and returned to the designated storage location.

5.3.10 Any spills or leaks of reagents or reference standards shall be cleaned up immediately according to the spill control procedures outlined in the laboratory safety manual.

5.4 Disposal of Reagents and Reference Standards

5.4.1 Expired or unused reagents and reference standards shall be disposed of in accordance with applicable environmental regulations and NovaThera Pharmaceuticals’ waste disposal procedures.

5.4.2 The QC Inspector shall consult the MSDS for each reagent to determine the appropriate disposal method.

5.4.3 Hazardous waste shall be collected in designated containers labeled with the appropriate hazard warnings.

5.4.4 The QC Inspector shall maintain a record of all disposed reagents and reference standards in the Reagent Log Book (RLB-01) or Reference Standard Log Book (RSLB-01). The record shall include the following information:

- Reagent/Reference Standard Name
- Internal Control Number
- Quantity Disposed
- Date of Disposal
- Disposal Method
- Name and Signature of QC Inspector

5.4.5 Empty reagent and reference standard containers shall be rinsed thoroughly (if applicable) and disposed of according to the waste disposal procedures.

5.5 Reference Standard Qualification and Use

5.5.1 Upon initial receipt of a Reference Standard, a formal qualification process must be completed by the QC Inspector. This includes:

- Verification of the Certificate of Analysis (CoA) against the Reference Standard label.
- Comparison of the CoA with the compendial requirements, if applicable (e.g., USP, EP).
- Performance of identity testing (e.g., IR Spectroscopy, HPLC) to confirm the identity of the Reference Standard.
- Determination of the potency or assay value of the Reference Standard, if required, against a qualified, previously approved Reference Standard.

5.5.2 The results of the qualification testing shall be documented in a Reference Standard Qualification Report, which shall be reviewed and approved by the QA Manager.

5.5.3 Only qualified Reference Standards shall be used for quantitative analysis.

5.5.4 The QC Inspector shall track the usage of each Reference Standard in the Reference Standard Log Book (RSLB-01), including the date of use, the quantity used, the method used, and the analyst's initials.

5.5.5 Reference Standards should be stored in a desiccator, if appropriate, to maintain their purity and stability.

5.5.6 Working Reference Standard solutions should be prepared fresh daily, unless otherwise justified and documented in the analytical method.

6.0 POST-PROCEDURE ACTIVITIES

6.1 The QC Inspector shall ensure that all work areas are clean and tidy after use.

6.2 The QC Inspector shall ensure that all equipment is cleaned and maintained according to the equipment SOPs.

6.3 The QC Inspector shall ensure that all documentation is complete and accurate.

6.4 The QC Inspector shall return all reagents and reference standards to their designated storage locations.

6.5 The Production Supervisor shall review the logbooks weekly and ensure that all entries are complete and accurate. Any discrepancies shall be investigated and resolved.

6.6 The QA Manager shall conduct periodic audits of the reagent and reference standard management system to ensure compliance with this SOP and applicable regulations.

6.7 The QA Manager shall review the temperature monitoring logs monthly to ensure that storage conditions are within the acceptable range.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE when handling reagents and reference standards.

7.2 Read and understand the MSDS for each reagent before use.

7.3 Handle reagents and reference standards in a well-ventilated area.

7.4 Avoid contact with skin, eyes, and clothing.

7.5 Do not ingest reagents or reference standards.

7.6 In case of contact with skin or eyes, flush with copious amounts of water for at least 15 minutes and seek medical attention.

7.7 In case of ingestion, seek medical attention immediately.

7.8 Do not mix incompatible chemicals.

7.9 Follow all safety guidelines outlined in the laboratory safety manual.

7.10 Be aware of the location of emergency equipment, such as eyewash stations and safety showers.

7.11 Any unusual occurrences, incidents, or accidents must be immediately reported to the QA Manager.

8.0 APPROVALS

Prepared By: QC Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
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