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Title:	Handling of Hazardous Materials and Waste Disposal	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Handling of Hazardous Materials and Waste Disposal

Category: Health, Safety & Environment

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure defines the safe and compliant handling, storage, and disposal of hazardous materials and waste generated during pharmaceutical manufacturing at NovaThera Pharmaceuticals, ensuring personnel safety, environmental protection, and adherence to regulatory requirements.

2.0 SCOPE

This SOP applies to all NovaThera Pharmaceuticals personnel involved in the handling, storage, transportation, and disposal of hazardous materials and waste generated during pharmaceutical manufacturing, research and development, quality control, and maintenance activities. It encompasses all hazardous chemicals, biological agents, and physical hazards present within the facility, and covers all product lines and batches manufactured at NovaThera Pharmaceuticals.

3.0 RESPONSIBILITY

QC Inspector: Inspects and verifies the proper labeling, storage, and disposal of hazardous materials and waste. Reports any discrepancies to the Production Supervisor and QA Manager.

Production Supervisor: Ensures that all personnel are trained on this SOP and comply with its requirements. Oversees the proper handling, storage, and disposal of hazardous materials and waste in their respective areas.

QA Manager: Reviews and approves this SOP and related documents. Monitors compliance with this SOP through audits and inspections. Investigates any deviations from this SOP.

Head of QA: Approves this SOP and any revisions. Ensures that the company has adequate resources to implement this SOP.

4.0 MATERIALS & EQUIPMENT

PPE: Chemical resistant gloves (nitrile or neoprene), safety goggles, face shields, respirators (as specified in the Safety Data Sheet (SDS)), lab coats, appropriate footwear (steel-toe if required).

Equipment: Spill kits (containing absorbent materials, neutralizers, and personal protective equipment), labeled containers for hazardous waste, transport carts, weighing scales, pH meters, temperature monitoring devices.

Documentation: Safety Data Sheets (SDS) for all hazardous materials, Hazardous Waste Disposal Log, Training Records, Incident Reports, Waste Manifests.

5.0 PROCEDURE

5.1 Identification and Classification of Hazardous Materials

5.1.1 All incoming materials must be assessed for potential hazards based on their SDS, physical properties, and intended use. The Production Supervisor shall ensure that an SDS is readily available for each hazardous material used.

5.1.2 The QC Inspector must verify that all incoming materials are properly labeled with the chemical name, hazard warnings, and supplier information.

5.1.3 If a material is classified as hazardous, it must be handled and stored in accordance with its SDS and this SOP.

5.1.4 The QA Manager shall maintain a list of all hazardous materials used in the facility.

5.1.5 The Production Supervisor shall ensure that secondary containers used for dispensing hazardous materials are properly labeled with the chemical name, hazard warnings, and any other relevant information.

5.2 Handling of Hazardous Materials

5.2.1 Before handling any hazardous material, personnel must review the SDS to understand the potential hazards and appropriate safety precautions.

5.2.2 Appropriate PPE, as specified in the SDS, must be worn at all times when handling hazardous materials.

5.2.3 Hazardous materials should be handled in well-ventilated areas or under a fume hood to minimize exposure to vapors or dust.

5.2.4 When transferring hazardous materials, use appropriate equipment such as pumps, funnels, or scoops to prevent spills and minimize exposure.

5.2.5 Spills of hazardous materials must be cleaned up immediately using a spill kit. The Production Supervisor shall document all spills in an incident report.

5.2.6 If a spill occurs, the area must be evacuated, and the appropriate emergency personnel must be notified.

5.2.7 When weighing hazardous materials, use a calibrated weighing scale (e.g., SCAL-01) and record the weight in the batch record.

5.2.8 When mixing hazardous materials, follow the instructions in the batch record and the SDS to prevent dangerous reactions.

5.2.9 For solvents used in the manufacturing process like the granulation stage with BLN-04 blender or the coating stage with the COA-01 coater, ensure proper grounding to avoid static discharge.

5.2.10 When using hazardous compressed gases, ensure that the cylinders are properly secured and handled with care.

5.3 Storage of Hazardous Materials

5.3.1 Hazardous materials must be stored in designated areas that are clearly marked and separated from other materials.

5.3.2 Storage areas must be well-ventilated and protected from heat, sparks, and open flames.

5.3.3 Incompatible materials must be stored separately to prevent dangerous reactions. Refer to the SDS for compatibility information.

5.3.4 Flammable materials must be stored in flammable storage cabinets that meet the requirements of NFPA 30.

5.3.5 Corrosive materials must be stored in acid-resistant cabinets or on acid-resistant shelving.

5.3.6 Hazardous materials must be stored in tightly closed containers that are properly labeled.

5.3.7 Storage areas must be inspected regularly by the QC Inspector to ensure that materials are properly stored and labeled.

5.3.8 The Production Supervisor shall maintain an inventory of all hazardous materials stored in the facility.

5.4 Handling of Biological Hazards

5.4.1 All biological hazards must be handled in accordance with biosafety guidelines and regulations.

5.4.2 Appropriate PPE, such as gloves, lab coats, and eye protection, must be worn when handling biological hazards.

5.4.3 Biological hazards must be handled in a biosafety cabinet to prevent the release of infectious agents.

5.4.4 Contaminated materials must be autoclaved or disinfected before disposal.

5.4.5 Spills of biological hazards must be cleaned up immediately using a disinfectant.

5.4.6 Personnel working with biological hazards must be trained on biosafety procedures.

5.5 Handling of Physical Hazards

5.5.1 Physical hazards such as sharps, broken glass, and compressed gases must be handled with care to prevent injuries.

5.5.2 Sharps must be disposed of in designated sharps containers.

5.5.3 Broken glass must be cleaned up with a broom and dustpan and disposed of in a designated container.

5.5.4 Compressed gas cylinders must be properly secured and handled with care.

5.5.5 Personnel working with machinery such as the SFT-02 sifter or TCP-01 tablet press must be trained on safe operating procedures.

5.6 Waste Disposal

5.6.1 Hazardous waste must be segregated from non-hazardous waste and disposed of in accordance with applicable regulations.

5.6.2 Hazardous waste containers must be properly labeled with the type of waste and the date of generation.

5.6.3 The QC Inspector must verify that all hazardous waste containers are properly labeled and sealed.

5.6.4 Hazardous waste must be stored in a designated area that is secured and protected from the elements.

5.6.5 A licensed hazardous waste disposal company must be used to transport and dispose of hazardous waste.

5.6.6 The Production Supervisor shall maintain records of all hazardous waste generated and disposed of.

5.6.7 Waste manifests must be completed and signed by both NovaThera Pharmaceuticals and the hazardous waste disposal company.

5.6.8 All waste disposal activities shall adhere to the guidelines outlined by the Central Pollution Control Board (CPCB) and the applicable State Pollution Control Board.

5.7 Training

5.7.1 All personnel who handle hazardous materials must receive training on this SOP and related safety procedures.

5.7.2 Training must include information on the hazards of the materials, safe handling procedures, PPE requirements, and emergency response procedures.

5.7.3 Training must be documented and records must be maintained by the Production Supervisor.

5.7.4 Refresher training must be provided periodically to ensure that personnel are up-to-date on safety procedures.

6.0 POST-[ACTIVITY] ACTIVITIES

6.1 After handling hazardous materials, personnel must wash their hands thoroughly with soap and water.

6.2 All PPE must be cleaned and stored properly.

6.3 The work area must be cleaned and decontaminated.

6.4 The Production Supervisor shall inspect the work area to ensure that it is safe and clean.

6.5 Any spills or incidents must be reported to the Production Supervisor and QA Manager.

6.6 All documentation, including batch records and waste disposal logs, must be completed and submitted to the QA department.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE when handling hazardous materials.

7.2 Work in well-ventilated areas or under a fume hood.

7.3 Avoid contact with skin and eyes.

7.4 Do not eat, drink, or smoke in areas where hazardous materials are handled.

7.5 Know the location of emergency equipment, such as eyewash stations and safety showers.

7.6 Report any spills or incidents to the Production Supervisor and QA Manager immediately.

7.7 In case of exposure, follow the first aid instructions in the SDS.

7.8 Familiarize yourself with the emergency response plan for the facility.

7.9 Never mix incompatible chemicals.

7.10 Properly label all containers.

7.11 Store hazardous materials in designated areas.

7.12 Handle compressed gas cylinders with care.

7.13 Regularly inspect safety equipment, such as respirators and eyewash stations.

7.14 Adhere to all applicable regulations and guidelines.

7.15 Conduct regular risk assessments to identify potential hazards and implement appropriate control measures.

7.16 Prior to using new or unfamiliar equipment, the Production Supervisor must ensure that all operating personnel receive adequate training on its safe operation.

7.17 Personnel working near equipment utilizing high voltages or currents must be trained in Lock-Out/Tag-Out (LOTO) procedures and familiar with emergency shut-off locations.

7.18 Ensure regular inspections of safety interlocks on equipment such as the TCP-01 tablet press and COA-01 coater and verify their proper function prior to each use.

8.0 APPROVALS

Prepared By: HSE Officer

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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