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Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Personal Protective Equipment (PPE) Requirements

Category: Health, Safety & Environment

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd., Pune, India

Department: Health, Safety & Environment (HSE)

Title: Personal Protective Equipment (PPE) Requirements

SOP No.: SOP-HSE-001

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1.0 PURPOSE

This Standard Operating Procedure (SOP) defines the requirements for the selection, use, maintenance, and storage of Personal Protective Equipment (PPE) at NovaThera Pharmaceuticals Pvt. Ltd. This procedure ensures the safety and health of all personnel involved in pharmaceutical manufacturing activities, minimizing potential exposure to hazards and complying with applicable Good Manufacturing Practices (GMP) and regulatory requirements, including 21 CFR Parts 210 and 211, ICH Q7, and relevant local regulations. The effective implementation of this SOP contributes to the quality objectives of NovaThera Pharmaceuticals by mitigating risks related to product contamination and personnel safety, thereby enhancing overall operational efficiency and product integrity. It aligns with risk-based approaches and quality by design principles to proactively address potential hazards within the manufacturing environment. This SOP also outlines procedures for risk assessment to identify necessary PPE and training requirements for proper PPE usage, ultimately fostering a safe and compliant work environment.

2.0 SCOPE

This SOP applies to all NovaThera Pharmaceuticals Pvt. Ltd. personnel, including employees, contractors, and visitors, who enter or work in any area where PPE is required. This includes, but is not limited to, manufacturing areas (e.g., raw material dispensing, granulation, compression, coating, encapsulation, filling, and packaging), quality control laboratories, maintenance areas, and warehouse

facilities. The scope encompasses all products manufactured at NovaThera Pharmaceuticals, regardless of dosage form (e.g., tablets, capsules, injectables, liquids, creams, and ointments), including Active Pharmaceutical Ingredients (APIs) and finished drug products. This SOP excludes office areas not directly involved in manufacturing, quality control, or maintenance activities. Adherence to this SOP ensures compliance with GMP guidelines, OSHA regulations, and other applicable health and safety regulations for all processes and materials used within the facility. The scope extends to the management of PPE inventory, inspection procedures, and disposal protocols to maintain a safe and compliant working environment, following ALCOA+ principles for data integrity and documentation.

3.0 RESPONSIBILITY

QC Inspector: The QC Inspector is responsible for verifying the proper use of PPE by personnel in controlled areas, documenting observations in relevant logs, reporting any deviations to the Production Supervisor or QA Manager, and ensuring that PPE meets the required quality standards. They will conduct routine inspections of PPE storage areas to confirm proper storage and availability of required equipment. The QC Inspector is responsible for recording and reporting the results of PPE inspections, using predefined metrics such as the percentage of personnel compliant with PPE usage and the number of identified PPE defects. This information will be used to identify areas for improvement and ensure ongoing compliance with PPE requirements. The QC Inspector also participates in the investigation of incidents related to PPE non-compliance and recommends corrective and preventive actions.

Production Supervisor: The Production Supervisor is responsible for ensuring that all personnel under their supervision comply with the requirements of this SOP, providing necessary training on PPE usage, enforcing adherence to PPE policies, addressing any PPE-related concerns, and immediately reporting any incidents or near misses to the QA Manager. They have the authority to stop production activities if PPE requirements are not met or if there is a safety concern. The Production Supervisor is also responsible for maintaining an adequate supply of PPE, ensuring that PPE is readily accessible, and verifying that PPE is properly stored and maintained. They will conduct regular safety meetings with their team to reinforce PPE requirements, discuss any relevant safety issues, and gather feedback on PPE effectiveness and comfort.

QA Manager: The QA Manager is responsible for the overall implementation and maintenance of this SOP, ensuring that it is up-to-date with current regulations and best practices, approving any changes to the SOP, conducting periodic audits to verify compliance, managing deviations related to PPE, and ensuring that appropriate corrective and preventive actions (CAPA) are implemented. The QA Manager will also review incident reports related to PPE non-compliance, analyze trends, and identify opportunities to improve PPE policies and procedures. They will work closely with the Head of QA to ensure that the PPE program is aligned with the overall quality management system and that resources are available to support its effective implementation. The QA Manager is responsible for maintaining the training records for all personnel on PPE usage and ensuring that training programs are regularly reviewed and updated to reflect changes in regulations or best practices.

Head of QA: The Head of QA is responsible for providing strategic oversight of the PPE program, ensuring alignment with regulatory requirements and industry standards, representing NovaThera Pharmaceuticals in regulatory inspections related to PPE, and ensuring that sufficient resources are allocated to support the effective implementation of this SOP. The Head of QA has the ultimate responsibility for ensuring that the PPE program is effective in protecting personnel and preventing product contamination. They will stay abreast

of changes in regulations and industry best practices and ensure that the PPE program is updated accordingly. The Head of QA will also review the results of audits and inspections related to PPE and ensure that any identified deficiencies are addressed promptly and effectively. They act as the primary liaison with regulatory agencies on matters related to PPE and will represent NovaThera Pharmaceuticals in any inspections or audits related to PPE.

4.0 MATERIALS & EQUIPMENT

PPE:

- Disposable Gloves: Nitrile gloves (powder-free), various sizes (S, M, L, XL), meeting ASTM D6319 standard.
- Safety Glasses/Goggles: Polycarbonate lenses, ANSI Z87.1 certified, with side shields or full seal.
- Respirators: N95 respirators (NIOSH approved), half-face respirators with appropriate cartridges for dust, fumes, and organic vapors. Selection based on risk assessment and exposure monitoring.
- Protective Clothing: Disposable Tyvek suits (coveralls), shoe covers, and head covers. Laundering of reusable garments per validated procedure.
- Hearing Protection: Earplugs (disposable and reusable) with an NRR of 25 dB or higher. Earmuffs for high-noise areas.
- Safety Shoes: Steel-toed shoes meeting ASTM F2413 standard, slip-resistant soles.
- Face Shields: Transparent face shields for protection against splashes and projectiles.
- Chemical Resistant Aprons/Suits: For handling corrosive or hazardous chemicals, compliant with EN 14605 or equivalent.

Equipment:

- Fit Testing Equipment: Quantitative or qualitative fit testing equipment for respirators, calibrated annually. Calibration records maintained electronically within the CMMS.
- Eye Wash Stations: Plumbed eyewash stations and portable eyewash bottles, inspected weekly. Inspection records maintained electronically.
- Safety Showers: Plumbed safety showers, inspected weekly. Inspection records maintained electronically.
- Air Monitoring Equipment: Equipment for measuring airborne contaminants (dust, vapors, gases), calibrated according to schedule. Calibration records maintained electronically within the CMMS.
- Inspection Mirrors: For visual inspection of PPE, especially in hard-to-reach areas.
- Disposal Containers: Designated containers for disposal of used PPE, labeled according to waste type.
- Laundering Equipment (if applicable): Industrial washing machines and dryers for reusable garments, validated for cleaning effectiveness. Validation records maintained electronically.

Documentation:

- PPE Hazard Assessment Form: A documented risk assessment outlining the potential hazards and required PPE for each area and task. Version controlled.

• PPE Issue Log: Record of PPE issued to personnel, including date, type, and quantity. Electronic format.

• PPE Inspection Log: Record of regular PPE inspections, including date, inspector, findings, and corrective actions. Electronic format.

• PPE Training Records: Documentation of personnel training on PPE selection, use, maintenance, and storage. Electronic format.

• Deviation Reports: Reports documenting any deviations from this SOP, including root cause analysis and corrective actions. Electronic format.

• CAPA Reports: Reports documenting corrective and preventive actions taken to address PPE-related issues. Electronic format.

• Change Control Requests: Documentation of any changes to this SOP or related procedures, including justification and approval. Electronic format.

Reagents/Chemicals:

• Cleaning Solutions: Mild detergents for cleaning reusable PPE. Grade: Laboratory grade.

• Disinfectants: EPA-registered disinfectants for sanitizing PPE. Grade: Pharmaceutical grade.

5.0 PROCEDURE

5.1 Pre-Activity Preparation

5.1.1 Review the applicable Standard Operating Procedures (SOPs) for the specific task or area where PPE is required. Ensure familiarity with potential hazards and required PPE. Document review in training records.

5.1.2 Conduct a visual inspection of the work area to identify any potential hazards that may require specific PPE (e.g., spills, sharp objects).

5.1.3 Select the appropriate PPE based on the hazard assessment and task requirements. Consult the PPE Hazard Assessment Form for guidance.

5.1.4 Verify that the selected PPE is clean, in good condition, and of the correct size. Inspect gloves for tears, safety glasses for scratches, and respirators for proper fit.

5.1.5 Ensure that all required equipment (e.g., fit testing equipment, eyewash stations) is readily available and in working order.

5.1.6 If using a respirator, conduct a user seal check to ensure a proper fit. Follow the manufacturer's instructions for the specific respirator model. Record the seal check result.

5.1.7 Verify that training records are up-to-date for the specific PPE being used. Training must include proper donning, doffing, use, maintenance, and storage procedures.

5.2 Donning of PPE

5.2.1 Wash and dry hands thoroughly before donning any PPE.

5.2.2 Don PPE in the following order (unless otherwise specified in the task-specific SOP):

- Shoe covers: Ensure complete coverage of shoes.
- Hair cover/beard cover (if applicable): Ensure all hair is contained.
- Tyvek suit/protective clothing: Ensure proper closure and sealing.
- Respirator (if required): Perform a user seal check.
- Safety glasses/goggles: Adjust for a secure and comfortable fit.
- Gloves: Ensure gloves overlap the sleeves of the protective clothing.

5.2.3 Visually inspect all PPE to ensure it is properly donned and provides adequate coverage. A second person should verify the correct donning procedure, if possible.

5.2.4 Document the donning of PPE in the appropriate logbook or electronic record.

5.3 Performing Task with PPE

5.3.1 Perform the assigned task according to the applicable SOPs.

5.3.2 Be aware of potential hazards and take necessary precautions to avoid exposure.

5.3.3 Regularly inspect PPE for damage or contamination during the task.

5.3.4 If PPE becomes damaged or contaminated, immediately stop the task, doff the contaminated PPE, and don new PPE. Dispose of the contaminated PPE properly.

5.3.5 Report any incidents or near misses to the Production Supervisor and QA Manager.

5.3.6 Avoid touching the face with gloved hands. If necessary, sanitize gloves before touching the face.

5.3.7 Maintain a clean and organized work area to minimize the risk of contamination.

5.4 In-Process Controls

5.4.1 Visual Inspection: The Production Supervisor will conduct hourly visual inspections to ensure that all personnel are wearing the correct PPE and that the PPE is in good condition. Record inspection findings in the production log.

5.4.2 Glove Integrity Check: The QC Inspector will conduct random glove integrity checks throughout the shift using a visual inspection method or a glove leak tester. Frequency: Every 2 hours. Acceptance Criteria: No visible tears, punctures, or leaks. Record inspection results in the QC inspection log.

5.4.3 Respirator Fit Check: For personnel wearing respirators, the Production Supervisor will conduct periodic spot checks to ensure proper respirator fit and seal. Frequency: Every 4 hours. Acceptance Criteria: Proper fit and seal as determined by a user seal check. Document checks in the production log.

5.4.4 Environmental Monitoring: Environmental monitoring will be conducted according to the environmental monitoring plan to assess the effectiveness of PPE in preventing product contamination. Samples will be collected and analyzed for microbial and particulate contamination. Acceptance Criteria: Within established alert and action limits. Record results in the environmental monitoring log.

5.4.5 Air Monitoring (if applicable): Air monitoring will be conducted in areas where there is a potential for exposure to airborne contaminants. Samples will be collected and analyzed for specific contaminants. Acceptance Criteria: Below established occupational exposure limits (OELs). Record results in the air monitoring log.

5.5 Doffing of PPE

5.5.1 Doff PPE in a designated area to minimize the risk of contamination.

5.5.2 Doff PPE in the following order (unless otherwise specified in the task-specific SOP):

- Shoe covers: Remove carefully to avoid spreading contamination.
- Gloves: Use a glove-in-glove technique to avoid touching the outer surface of the gloves with bare hands.
- Safety glasses/goggles: Remove carefully to avoid touching the lenses.
- Respirator (if required): Remove carefully to avoid touching the contaminated surface.
- Tyvek suit/protective clothing: Remove carefully, avoiding contact with the inner surface.
- Hair cover/beard cover (if applicable): Remove carefully to avoid spreading contamination.

5.5.3 Dispose of disposable PPE in the designated waste containers.

5.5.4 Wash and dry hands thoroughly after doffing PPE.

5.5.5 Document the doffing of PPE in the appropriate logbook or electronic record.

6.0 POST-ACTIVITY PROCEDURES

6.1 Review data collected during the activity to ensure that all in-process controls were met and that there were no deviations.

6.2 Clean and disinfect reusable PPE according to the manufacturer's instructions and the facility's cleaning and disinfection SOP.

6.3 Store reusable PPE in a designated area that is clean, dry, and protected from contamination.

6.4 Inspect reusable PPE for damage before storing it. Replace any damaged PPE.

6.5 Dispose of disposable PPE in the designated waste containers according to the facility's waste management SOP.

6.6 Complete all required documentation, including logbooks, inspection records, and deviation reports. Ensure that all data is accurate, complete, and attributable. Follow ALCOA+ principles.

6.7 Report any incidents or near misses to the Production Supervisor and QA Manager.

6.8 Conduct a debriefing session with the team to identify any areas for improvement in the PPE program or the task-specific SOP.

6.9 Review environmental monitoring data to assess the effectiveness of PPE in preventing product contamination.

7.0 SAFETY PRECAUTIONS

7.1 Conduct a risk assessment to identify potential hazards and determine the appropriate PPE for each task and area. Document the risk assessment in the PPE Hazard Assessment Form.

7.2 Provide adequate training to all personnel on the proper selection, use, maintenance, and storage of PPE. Document training in the personnel training records.

7.3 Enforce strict adherence to PPE requirements.

7.4 Regularly inspect PPE for damage and replace it as needed.

7.5 Provide readily accessible eyewash stations and safety showers in areas where there is a risk of chemical exposure. Inspect weekly, documented electronically.

7.6 Ensure adequate ventilation in areas where there is a potential for exposure to airborne contaminants.

7.7 Implement a respiratory protection program that includes fit testing, medical evaluations, and training.

7.8 Establish emergency procedures for handling spills, chemical exposures, and other incidents.

7.9 Provide appropriate first aid supplies and training.

7.10 Report all incidents and near misses to the Production Supervisor and QA Manager.

7.11 Ensure that all personnel are aware of the location of emergency exits and assembly points.

7.12 Maintain a clean and organized work area to minimize the risk of accidents.

7.13 Regularly review and update safety procedures and PPE requirements.

8.0 QUALITY CONTROL MEASURES

8.1 PPE Inspection: All PPE will be visually inspected before each use for damage, contamination, or defects. The inspection will be documented in the PPE Inspection Log. Acceptance Criteria: PPE must be clean, undamaged, and free of defects.

8.2 Glove Integrity Testing: Random glove integrity testing will be conducted on a regular basis to ensure that gloves are providing adequate protection. Frequency: Weekly. Method: Water leak test or air inflation test. Acceptance Criteria: No leaks or punctures.

8.3 Respirator Fit Testing: Respirator fit testing will be conducted annually for all personnel who are required to wear respirators. The fit testing will be conducted according to OSHA regulations. Acceptance Criteria: Passing fit test result.

8.4 Environmental Monitoring: Environmental monitoring will be conducted in controlled areas to assess the effectiveness of PPE in preventing product contamination. Samples will be collected and analyzed for microbial and particulate contamination. Frequency: According to the environmental monitoring plan. Acceptance Criteria: Within established alert and action limits.

8.5 Air Monitoring (if applicable): Air monitoring will be conducted in areas where there is a potential for exposure to airborne contaminants. Samples will be collected and analyzed for specific contaminants. Frequency: According to the air monitoring plan. Acceptance Criteria: Below established occupational exposure limits (OELs).

8.6 Review of Documentation: All documentation related to PPE (e.g., inspection logs, training records, deviation reports) will be reviewed regularly by the QA Manager to ensure accuracy and completeness.

8.7 Audits: Periodic audits will be conducted to verify compliance with this SOP and relevant regulations. The audits will be conducted by the QA department or an external auditor.

9.0 DOCUMENTATION AND RECORDS

9.1 All activities performed under this SOP must be documented accurately and completely.

9.2 All records must be legible, permanent, and contemporaneous.

9.3 All records must be signed and dated by the person performing the activity.

9.4 All electronic records must be protected from unauthorized access, alteration, or deletion. Follow ALCOA+ principles for data integrity.

9.5 The following records must be maintained:

- PPE Hazard Assessment Form
- PPE Issue Log

- PPE Inspection Log
- PPE Training Records
- Deviation Reports
- CAPA Reports
- Change Control Requests
- Environmental Monitoring Records
- Air Monitoring Records (if applicable)
- Respirator Fit Testing Records

9.6 Records must be retained for the period specified in the facility's record retention policy.

9.7 Electronic records must be backed up regularly to prevent data loss.

9.8 Access to records must be controlled according to the facility's security procedures.

9.9 Any changes to records must be documented and justified.

9.10 All documentation must be reviewed and approved by the QA Manager.

10.0 DEVIATIONS AND CORRECTIVE ACTIONS

10.1 Any deviation from this SOP must be documented in a deviation report.

10.2 The deviation report must include the following information:

- Date and time of the deviation
- Description of the deviation
- Root cause of the deviation
- Impact of the deviation
- Corrective actions taken
- Preventive actions to prevent recurrence
- Signature and date of the person reporting the deviation

10.3 The deviation report must be reviewed and approved by the QA Manager.

10.4 Corrective and preventive actions (CAPA) must be implemented to address the root cause of the deviation and prevent recurrence.

10.5 CAPA must be documented in a CAPA report.

10.6 The CAPA report must include the following information:

- Description of the CAPA
- Person responsible for implementing the CAPA
- Target completion date
- Actual completion date
- Verification of effectiveness
- Signature and date of the person completing the CAPA

10.7 The CAPA report must be reviewed and approved by the QA Manager.

10.8 All deviations and CAPA must be tracked in a deviation tracking system.

11.0 TRAINING REQUIREMENTS

11.1 All personnel who are required to use PPE must be trained on the proper selection, use, maintenance, and storage of PPE.

11.2 Training must be provided upon initial assignment and annually thereafter.

11.3 Training must include the following topics:

- Potential hazards in the workplace
- Types of PPE available
- Proper selection of PPE
- Proper donning and doffing of PPE
- Proper use of PPE
- Proper maintenance and storage of PPE
- Limitations of PPE
- Emergency procedures
- Fit testing (for respirators)

11.4 Training must be documented in the personnel training records.

11.5 Training effectiveness must be assessed through written tests, practical demonstrations, or other methods.

11.6 Training materials must be reviewed and updated regularly to reflect changes in regulations or best practices.

12.0 REVIEW AND REVISION

12.1 This SOP will be reviewed at least annually or more frequently if necessary (e.g., after a significant incident or a change in regulations).

12.2 The review will be conducted by the QA Manager in consultation with the Head of QA, Production Supervisor and representatives from the Health and Safety Department.

12.3 Any revisions to this SOP must be documented in a change control request.

12.4 The change control request must include the following information:

- Justification for the change
- Description of the change
- Impact of the change
- Affected personnel
- Training requirements
- Approval signatures

12.5 All changes to this SOP must be approved by the QA Manager and the Head of QA.

12.6 The revised SOP must be distributed to all affected personnel.

12.7 Obsolete versions of the SOP must be removed from circulation.

13.0 APPROVALS

Prepared By: HSE Officer

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Controlled Document Notice

Document Approval

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

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