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Title:	Emergency Response and Evacuation Procedure	Version:	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
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Emergency Response and Evacuation Procedure

Category: Health, Safety & Environment

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1.0 PURPOSE

This procedure defines the steps to be taken by all personnel at NovaThera Pharmaceuticals Pvt. Ltd. in the event of an emergency requiring partial or complete evacuation of the facility. The purpose is to ensure the safety of all personnel, minimize potential damage to property and equipment, and comply with applicable regulatory requirements during pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all NovaThera Pharmaceuticals Pvt. Ltd. employees, contractors, and visitors present within the facility, including all manufacturing areas, laboratories, offices, and storage areas. This procedure covers all potential emergencies including, but not limited to, fires, chemical spills, explosions, natural disasters (earthquakes, floods), medical emergencies, security threats, and power outages. It applies to all applicable products and batches manufactured or stored on-site.

3.0 RESPONSIBILITY

QC Inspector: To promptly report any emergency situation observed to the Production Supervisor or designated emergency contact. To follow evacuation procedures as directed by

the emergency response team.

Production Supervisor: To assess the reported emergency, initiate the emergency response plan, and coordinate evacuation procedures. To communicate the nature of the emergency and evacuation instructions to personnel within their area of responsibility. To ensure that critical equipment is safely shut down when possible and appropriate. To maintain a list of personnel assigned to their area and confirm their safe evacuation.

QA Manager: To ensure that this SOP is reviewed and updated as necessary. To participate in emergency response drills and provide feedback for improvement. To ensure documentation related to emergency events is properly maintained and controlled. To provide support and guidance to the Production Supervisor during emergency situations. To assess the impact of the emergency on product quality and compliance.

Head of QA: To approve this SOP and any subsequent revisions. To provide overall oversight of the emergency response program at NovaThera Pharmaceuticals Pvt. Ltd. To ensure that adequate resources are available for emergency response and preparedness. To communicate with regulatory agencies and senior management as required. To investigate any deviations related to the emergency response and implement corrective and preventive actions (CAPA).

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, safety shoes, gloves (appropriate for potential hazards), high-visibility vests, dust masks, self-contained breathing apparatus (SCBA - for trained personnel only).

Equipment: Fire extinguishers (various types based on hazard class), first aid kits, emergency eyewash stations, emergency showers, spill kits (chemical and biological), flashlights, bullhorns/megaphones, two-way radios, automated external defibrillator (AED), emergency power generator (GEN-01), fire alarm system (FAS-01), public address system (PAS-01).

Documentation: Emergency contact list, evacuation maps, incident report forms, personnel attendance records, equipment shutdown procedures, spill response procedures, first aid logbook, training records for emergency response personnel.

5.0 PROCEDURE

5.1 Discovery of an Emergency

5.1.1 Any employee who discovers a potential emergency (e.g., fire, chemical spill, injury, security breach) shall immediately assess the situation to the best of their ability, without putting themselves at undue risk.

5.1.2 The employee shall immediately report the emergency to the Production Supervisor or designated emergency contact using the fastest and most reliable method available (e.g., telephone, two-way radio, or in person). The report shall include the nature and location of the emergency, any known hazards, and any injuries.

5.1.3 If the emergency poses an immediate threat to life or safety, the employee shall activate the nearest fire alarm pull station (located throughout the facility) and evacuate the area immediately.

5.1.4 The QC Inspector, upon notification of an emergency, will cease all ongoing testing activities and secure any samples or data in a safe manner, if time and safety permit.

5.1.5 In case of fire, the employee should use a fire extinguisher only if trained and the fire is small and contained. Ensure the appropriate type of extinguisher is used (e.g., Class A, B, C, or D). If unsure, evacuate immediately.

5.2 Emergency Assessment and Activation

5.2.1 Upon receiving a report of an emergency, the Production Supervisor shall immediately assess the situation, considering the information provided and any available monitoring data (e.g., fire alarm system panel).

5.2.2 If the Production Supervisor determines that an emergency exists that requires evacuation, they shall activate the emergency response plan. This may involve activating the fire alarm system, making announcements over the public address system (PAS-01), and contacting the designated emergency response team.

5.2.3 The Production Supervisor will consult the emergency contact list to notify relevant personnel, including the QA Manager and Head of QA.

5.2.4 The Production Supervisor shall determine the scope of the evacuation, whether it is a partial evacuation of a specific area or a full evacuation of the entire facility.

5.2.5 If the emergency involves a chemical spill, the Production Supervisor shall consult the Safety Data Sheet (SDS) for the spilled chemical and initiate appropriate spill control measures, using the appropriate spill kit.

5.3 Evacuation Procedure

5.3.1 Upon hearing the evacuation alarm or receiving instructions to evacuate, all personnel shall immediately cease their activities and proceed to the designated evacuation assembly point(s).

5.3.2 Personnel shall follow the designated evacuation routes, as indicated on the evacuation maps posted throughout the facility. These maps clearly outline primary and secondary evacuation routes.

5.3.3 The Production Supervisor will ensure all equipment (BLN-04, TCP-01, SFT-02) is shut down safely in their respective areas, if safe to do so.

5.3.4 Personnel shall assist any individuals who may require assistance, such as those with mobility impairments or those who are injured.

5.3.5 Personnel shall not use elevators during an evacuation.

5.3.6 Personnel shall not re-enter the building until authorized by the Production Supervisor or designated emergency response personnel.

5.3.7 The Production Supervisor shall ensure that all visitors are accounted for and safely evacuated.

5.3.8 Production Supervisor should grab the personnel attendance records, if possible, on the way to the evacuation point.

5.4 Assembly and Accountability

5.4.1 Upon arrival at the designated evacuation assembly point, personnel shall report to the Production Supervisor or designated roll call taker.

5.4.2 The Production Supervisor shall conduct a roll call to ensure that all personnel are accounted for.

5.4.3 Any missing personnel shall be immediately reported to the emergency response team.

5.4.4 The Production Supervisor shall maintain communication with the emergency response team and provide updates on the status of the evacuation and any missing personnel.

5.4.5 Personnel shall remain at the assembly point until authorized to return to the building or dismissed by the Production Supervisor or designated emergency response personnel.

5.4.6 The Production Supervisor will document the time of arrival at the assembly point, the names of all personnel present, and any missing personnel.

5.5 Emergency Response (Fire, Chemical Spill, Medical Emergency)

5.5.1 Fire: If a fire is discovered, and it is safe to do so, use the appropriate fire extinguisher to attempt to extinguish the fire. If the fire cannot be extinguished quickly, evacuate the area and activate the fire alarm. Contact the fire department immediately. Ensure all personnel are evacuated from the affected area. Trained personnel can use the SCBA (self-contained

breathing apparatus) to assist in rescue operations if needed, but only if properly trained and equipped.

5.5.2 Chemical Spill: If a chemical spill occurs, consult the SDS for the spilled chemical. Wear appropriate PPE (gloves, safety glasses, respirator if necessary). Contain the spill using absorbent materials from the spill kit. Clean up the spill according to the SDS instructions. Dispose of the contaminated materials properly. Report the spill to the environmental health and safety department.

5.5.3 Medical Emergency: If a medical emergency occurs, provide first aid as necessary. Call for medical assistance immediately. Do not move the injured person unless it is necessary to remove them from danger. If the person is unresponsive, check for breathing and pulse. If necessary, administer CPR and use the AED if available. Provide the medical responders with information about the person's condition and the circumstances of the injury or illness. The first aid logbook must be filled out detailing the incident and treatment given.

5.6 Power Outage

5.6.1 In the event of a power outage, the emergency power generator (GEN-01) should automatically activate within [Specify Time, e.g., 10 seconds].

5.6.2 The Production Supervisor will assess the impact of the power outage on ongoing operations and determine whether a partial or full shutdown of equipment is necessary.

5.6.3 Critical equipment, such as refrigerators and freezers used for storing temperature-sensitive materials, should be monitored closely to ensure that temperatures remain within acceptable limits.

5.6.4 If the power outage is prolonged, the Production Supervisor will coordinate with maintenance personnel to troubleshoot the problem and restore power as quickly as possible.

5.6.5 The QA Manager will assess the impact of the power outage on product quality and compliance and determine whether any corrective actions are necessary.

6.0 POST-EVACUATION ACTIVITIES

6.1 The Production Supervisor, in coordination with the QA Manager and Head of QA, will assess the damage to the facility and equipment.

6.2 No personnel will be allowed to re-enter the facility until it has been declared safe by the Production Supervisor and/or emergency response personnel (e.g., fire department, police).

6.3 The QA Manager will assess the impact of the emergency on product quality and compliance, and determine the need for quarantine, rework, or rejection of affected materials.

6.4 An incident report will be prepared documenting the details of the emergency, the actions taken, and any resulting damage or injuries.

6.5 The Head of QA will initiate a root cause analysis to identify the cause of the emergency and implement corrective and preventive actions (CAPA) to prevent recurrence.

6.6 The emergency response plan will be reviewed and updated as necessary, based on the lessons learned from the incident.

6.7 The Production Supervisor will ensure that all equipment is inspected and tested before being returned to service.

6.8 The QC Inspector will re-qualify any equipment or instruments that may have been affected by the emergency.

6.9 The QA Manager will review all documentation related to the emergency and ensure that it is properly maintained and controlled.

6.10 The Head of QA will communicate with regulatory agencies and senior management as required, providing updates on the status of the recovery and any potential impact on product supply.

7.0 SAFETY PRECAUTIONS

7.1 All personnel must be familiar with the location of fire extinguishers, emergency exits, and evacuation assembly points.

7.2 Fire extinguishers must be inspected regularly and maintained in good working order.

7.3 Emergency exits must be kept clear and unobstructed at all times.

- 7.4 Personnel must wear appropriate PPE when handling hazardous materials or operating equipment.
- 7.5 All spills must be cleaned up promptly and properly.
- 7.6 All injuries must be reported immediately to the Production Supervisor.
- 7.7 The SCBA should only be used by trained and certified personnel.
- 7.8 During an evacuation, remain calm and follow the instructions of the Production Supervisor and emergency response personnel.
- 7.9 Do not attempt to fight a fire unless you are trained and equipped to do so.
- 7.10 Be aware of your surroundings and report any potential hazards to the Production Supervisor.
- 7.11 In case of chemical exposure, immediately flush the affected area with water for at least 15 minutes and seek medical attention.
- 7.12 Follow all safety guidelines and procedures outlined in the NovaThera Pharmaceuticals Pvt. Ltd. safety manual.

8.0 APPROVALS

Prepared By: Health and Safety Officer

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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Prepared by:			
Reviewed by (QA):			
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