Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-ENG-005
Title:	Equipment Breakdown and Repair Procedure	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Equipment Breakdown and Repair Procedure

Category: Engineering & Maintenance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Engineering & Maintenance

Title: Equipment Breakdown and Repair Procedure

SOP No.: SOP-ENG-005

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

This procedure defines the steps to be taken in the event of equipment breakdown in pharmaceutical manufacturing at NovaThera Pharmaceuticals, to ensure prompt response, appropriate repair, thorough documentation, and adherence to Good Manufacturing Practices (GMP) to maintain product quality and prevent recurrence of failures. This SOP also provides guidance for initiating investigations, implementing corrective and preventative actions (CAPA), and returning the equipment to a validated state for continued use.

2.0 SCOPE

This SOP applies to all equipment used in pharmaceutical manufacturing, including but not limited to production, packaging, laboratory, and utility equipment at NovaThera Pharmaceuticals Pvt. Ltd. This includes, but is not limited to, blenders (e.g., BLN-04), tablet presses (e.g., TCP-01), sifters (e.g., SFT-02), HVAC systems, water systems, and analytical instruments. This procedure covers activities from the initial identification of a breakdown through to the return of the equipment to routine use and applies to all products manufactured at the facility. This procedure excludes routine maintenance activities described in separate SOPs.

3.0 RESPONSIBILITY

QC Inspector:

- Performs visual inspection of repaired equipment.
- Reviews and approves relevant sections of the equipment breakdown and repair documentation.
- Performs necessary sampling and testing post-repair, as required.

Production Supervisor:

- Immediately reports any equipment breakdown to the Engineering Department.
- Provides information about the breakdown, including symptoms, time of occurrence, and potential impact on production.
- Coordinates with the Engineering Department to schedule repairs.
- Ensures the work area around the broken equipment is safe and secured.
- Reviews and approves the equipment breakdown and repair documentation.
- Ensures proper cleaning and sanitation of the equipment and surrounding area after repair.

QA Manager:

- Reviews and approves equipment breakdown reports, repair records, and deviation reports.
- Ensures that all repairs are performed in accordance with GMP and company procedures.
- Determines the need for investigations and corrective and preventative actions (CAPA).
- Oversees the implementation of CAPA.
- Assesses the impact of the breakdown and repair on product quality.
- Approves the return of the equipment to service.

Head of QA:

- Provides final approval for major equipment repairs or modifications.
- Oversees investigations into critical equipment failures.
- Ensures that the equipment breakdown and repair procedure is followed.
- Provides guidance on complex quality issues related to equipment breakdown and repair.
- Reviews and approves CAPA plans related to equipment failures.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses or goggles
- Safety shoes
- Gloves (appropriate for the task, e.g., nitrile, latex, cut-resistant)
- Hearing protection (if required)
- Dust mask or respirator (if required)

Equipment:

- General tools (e.g., screwdrivers, wrenches, pliers, multimeters)
- Specific tools required for the equipment being repaired (refer to equipment manuals)
- Cleaning supplies (e.g., isopropyl alcohol, lint-free cloths, detergents)
- Calibration standards (as required)
- Lubricants (as specified in equipment manuals)
- Locking and tagging (LOTO) equipment
- Personal Protective Equipment (PPE) as identified in Section 4.0

Documentation:

- Equipment Breakdown Report Form (FRM-ENG-005-01)
- Equipment Repair Record Form (FRM-ENG-005-02)
- Deviation Report Form (FRM-QA-001-01)
- Maintenance Logbook (LOG-ENG-001)
- Equipment-specific manuals and SOPs
- Calibration records
- Validation protocols and reports
- Change Control Request Form (FRM-QA-003-01)

5.0 PROCEDURE

5.1 Initial Response and Reporting

5.1.1 Upon detection of equipment malfunction or breakdown, the Production Supervisor immediately stops operation of the equipment.

5.1.2 The Production Supervisor assesses the immediate safety of the area and takes necessary precautions to prevent injury to personnel. This includes shutting down power to the equipment if necessary.

5.1.3 The Production Supervisor completes the Equipment Breakdown Report Form (FRM-ENG-005-01), providing details of the breakdown, including the date, time, equipment name and code (e.g., BLN-04), a description of the problem, and any potential impact on product quality or

safety.

5.1.4 The Production Supervisor immediately notifies the Engineering Department and QA Manager of the breakdown.

5.1.5 The Engineering Department acknowledges receipt of the report and assigns a qualified technician to investigate the breakdown.

5.1.6 The equipment must be tagged out of service with a “Do Not Operate” tag and locked out (LOTO) as per the site LOTO procedure.

5.2 Investigation and Diagnosis

5.2.1 The assigned Engineering technician visually inspects the equipment and surrounding area to identify the cause of the breakdown.

5.2.2 The Engineering technician troubleshoots the equipment using appropriate diagnostic tools and techniques, following the equipment manufacturer's manual and relevant SOPs.

5.2.3 The Engineering technician documents the findings of the investigation, including the root cause of the breakdown, in the Equipment Repair Record Form (FRM-ENG-005-02).

5.2.4 If the root cause cannot be immediately determined, the Engineering technician will consult with the Engineering Supervisor or other qualified personnel for further guidance.

5.2.5 If the breakdown is suspected to be related to a deviation from standard operating procedures or GMP requirements, a Deviation Report Form (FRM-QA-001-01) must be initiated by the Production Supervisor and submitted to the QA Manager for review.

5.3 Repair and Maintenance

5.3.1 Based on the diagnosis, the Engineering technician determines the necessary repairs or replacements required.

5.3.2 The Engineering technician procures the necessary parts or materials, ensuring that they meet the specified requirements and quality standards. Only approved vendors and parts must be used.

5.3.3 Before commencing repairs, the Engineering technician isolates the equipment from all power sources and ensures that all hazardous materials are removed from the area. The equipment must be locked and tagged out (LOTO) to prevent accidental start-up.

5.3.4 The Engineering technician performs the necessary repairs or replacements according to the equipment manufacturer's manual and relevant SOPs.

5.3.5 During the repair process, the Engineering technician ensures that all work is performed in a clean and controlled environment to prevent contamination.

5.3.6 The Engineering technician documents all repairs and replacements performed in the Equipment Repair Record Form (FRM-ENG-005-02), including the date, time, description of the work performed, parts replaced, and any observations.

5.3.7 After completion of the repairs, the Engineering technician performs a visual inspection of the equipment to ensure that all components are properly installed and functioning correctly.

5.3.8 The Engineering technician performs functional testing of the equipment to verify that it is operating within the specified parameters.

5.3.9 The functional testing should follow documented procedures and acceptance criteria.

5.4 Cleaning and Sanitation

5.4.1 Following the completion of repairs and functional testing, the Production Supervisor ensures that the equipment and surrounding area are thoroughly cleaned and sanitized according to the established cleaning procedures and SOPs.

5.4.2 Cleaning and sanitization agents must be approved for use in pharmaceutical manufacturing and must be used according to the manufacturer's instructions.

5.4.3 The cleaning process must remove any debris, lubricants, or other materials that may have been introduced during the repair process.

5.4.4 The effectiveness of the cleaning process must be verified by visual inspection and, if necessary, by analytical testing.

5.5 Quality Control and Release

5.5.1 After cleaning and sanitation, the QC Inspector performs a visual inspection of the repaired equipment to ensure that it meets the required cleanliness standards and is free from any visible defects.

5.5.2 If required, the QC Inspector performs sampling and testing of the equipment to verify that it meets the specified quality requirements. This may include testing for residual cleaning agents, microbial contamination, or other relevant parameters.

5.5.3 The QC Inspector reviews the Equipment Breakdown Report Form (FRM-ENG-005-01) and Equipment Repair Record Form (FRM-ENG-005-02) to ensure that all repairs and testing have been properly documented.

5.5.4 The QA Manager reviews the equipment breakdown and repair documentation, including the Equipment Breakdown Report Form (FRM-ENG-005-01), Equipment Repair Record Form (FRM-ENG-005-02), Deviation Report Form (FRM-QA-001-01) (if applicable), and QC inspection reports.

5.5.5 The QA Manager assesses the impact of the breakdown and repair on product quality and determines whether any further investigation or corrective action is required.

5.5.6 If the QA Manager is satisfied that the equipment has been properly repaired and that the repair does not pose a risk to product quality, the QA Manager approves the return of the equipment to service.

5.6 Equipment Return to Service

5.6.1 Once the QA Manager has approved the return of the equipment to service, the Production Supervisor removes the “Do Not Operate” tag and LOTO.

5.6.2 The Production Supervisor updates the equipment maintenance logbook (LOG-ENG-001) with details of the breakdown, repair, and return to service.

5.6.3 The Production Supervisor ensures that all relevant personnel are informed that the equipment is back in service.

5.6.4 Before the equipment is used for production, the Production Supervisor performs a final check to ensure that it is operating correctly and

that all safety features are functioning properly.

5.7 Calibration and Validation

5.7.1 If the repair or replacement involved components that affect the calibration of the equipment, the Engineering technician performs a recalibration of the equipment according to the established calibration procedures.

5.7.2 Calibration records must be updated to reflect the recalibration.

5.7.3 If the repair or replacement involved significant changes to the equipment that could affect its validated state, a revalidation of the equipment must be performed according to the established validation protocols. This determination is made by the QA Manager and the Head of QA.

5.7.4 Revalidation protocols must be approved by the QA Manager and the Head of QA before execution.

5.7.5 Revalidation reports must be reviewed and approved by the QA Manager and the Head of QA.

5.8 Change Control

5.8.1 If the repair or replacement involved a change to the equipment that is not covered by existing procedures or specifications, a Change Control Request Form (FRM-QA-003-01) must be initiated and approved according to the site change control procedure.

5.8.2 The change control process must assess the potential impact of the change on product quality, safety, and regulatory compliance.

5.8.3 The change control process must include appropriate risk assessments, testing, and documentation.

6.0 POST-REPAIR ACTIVITIES

6.1 The QA Manager reviews all documentation related to the equipment breakdown and repair, including the Equipment Breakdown Report Form (FRM-ENG-005-01), Equipment Repair Record Form (FRM-ENG-005-02), Deviation Report Form (FRM-QA-001-01) (if applicable), QC inspection reports, calibration records, and validation reports.

6.2 The QA Manager determines whether any further investigation or corrective action is required to prevent recurrence of the breakdown.

6.3 If a corrective and preventative action (CAPA) is required, the QA Manager initiates a CAPA investigation and assigns responsibility for implementing the CAPA.

6.4 The QA Manager monitors the implementation of the CAPA and verifies its effectiveness.

6.5 All documentation related to the equipment breakdown, repair, and CAPA is archived according to the document retention policy.

6.6 The Engineering Department analyzes the equipment breakdown data to identify trends and patterns and to develop preventive maintenance strategies to improve equipment reliability.

7.0 SAFETY PRECAUTIONS

7.1 Prior to any maintenance or repair activity, ensure that the equipment is de-energized and locked out/tagged out (LOTO) according to the site LOTO procedure.

7.2 Always wear appropriate personal protective equipment (PPE), including safety glasses, gloves, and safety shoes.

7.3 Use caution when working with tools and equipment. Follow the manufacturer's instructions and use the correct tool for the job.

7.4 Be aware of potential hazards, such as electrical shock, moving parts, and hazardous materials.

7.5 Do not attempt to repair equipment unless you are properly trained and qualified.

7.6 If you are unsure about any aspect of the repair, consult with a qualified technician or supervisor.

7.7 Ensure that the work area is well-ventilated and free from obstructions.

7.8 Dispose of waste materials properly, according to the site waste disposal procedures.

7.9 Report any accidents or injuries immediately to the supervisor.

7.10 Follow all applicable safety regulations and guidelines.

8.0 APPROVALS

Prepared By: Engineering Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

This is a controlled document. Unauthorized reproduction, distribution, or alteration is prohibited. Ensure you are using the latest approved version.

Document Approval

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

Document Control Information

Document ID: SOP-ENG-005

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System