

Document Type:	Standard Operating Procedure (SOP)	SOP Code:	SOP-PKG-001
Title:	Operation, Cleaning, and Maintenance of the Blister Packaging Machine	Version:	Machine1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
Location:	Pune, India	Review Date:	2026-01-01

Operation, Cleaning, and Maintenance of the Blister Packaging Machine

Category: Packaging

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure outlines the standardized steps for the safe and efficient operation, cleaning, and maintenance of the blister packaging machine (BPM-01) at NovaThera Pharmaceuticals Pvt. Ltd., ensuring compliance with current Good Manufacturing Practices (cGMP) in pharmaceutical manufacturing. It provides detailed instructions to maintain the integrity of the equipment and prevent product contamination, ensuring the quality of the packaged pharmaceutical products.

2.0 SCOPE

This SOP applies to all personnel involved in the operation, cleaning, and maintenance of the blister packaging machine (BPM-01) used for packaging solid oral dosage forms, including tablets and capsules, at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. It covers all applicable products and batches packaged using this equipment and applies to both routine operations and preventative maintenance activities. This SOP excludes any repairs requiring specialized technical expertise that is outside the scope of routine operator maintenance.

3.0 RESPONSIBILITY

QC Inspector:

- Inspects the cleaned and assembled blister packaging machine (BPM-01) prior to use to ensure it meets the required cleanliness standards.
- Performs in-process quality checks during the packaging process to verify seal integrity, correct printing, and proper product placement in blisters.
- Documents all inspection results accurately and promptly.
- Verifies the completion of cleaning and maintenance activities as per the checklist.

Production Supervisor:

- Ensures that all personnel operating, cleaning, and maintaining the blister packaging machine (BPM-01) are adequately trained on this SOP.
- Oversees the packaging process to ensure adherence to this SOP and all applicable cGMP regulations.
- Schedules and coordinates routine maintenance activities.
- Investigates and resolves any deviations or issues that arise during the packaging process.
- Ensures that the machine logbook is properly maintained.

QA Manager:

- Reviews and approves this SOP and any subsequent revisions.
- Ensures that the training program for personnel operating, cleaning, and maintaining the blister packaging machine (BPM-01) is adequate and up-to-date.
- Audits the packaging process to ensure compliance with this SOP and all applicable cGMP regulations.
- Reviews and approves deviation reports related to the blister packaging machine (BPM-01).
- Oversees the validation and qualification activities related to the blister packaging machine (BPM-01).

Head of QA:

- Provides final approval for this SOP and any subsequent revisions.
- Ensures the overall quality system is maintained to a high standard and complies with regulatory requirements.
- Oversees the implementation of this SOP and its effectiveness in maintaining product quality and cGMP compliance.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Disposable gloves
- Dust mask

- Hairnet
- Cleanroom gown/lab coat
- Shoe covers

Equipment:

- Blister Packaging Machine (BPM-01)
- Vacuum cleaner with HEPA filter
- Lint-free wipes
- Cleaning solutions (e.g., 70% Isopropyl Alcohol, Detergent solution – Refer to approved cleaning validation protocol)
- Calibrated torque wrench (TRQ-01)
- Maintenance tools (e.g., screwdrivers, wrenches, Allen keys)
- Compressed air supply with filter
- Light source for inspection

Documentation:

- Blister Packaging Machine (BPM-01) Operation Manual
- Blister Packaging Machine (BPM-01) Cleaning Log
- Blister Packaging Machine (BPM-01) Maintenance Log
- Batch Packaging Record (BPR)
- Equipment Usage Log
- Deviation Report Form
- Cleaning Validation Protocol
- Material Safety Data Sheets (MSDS) for all cleaning agents
- Preventative Maintenance Schedule

5.0 PROCEDURE

5.1 Pre-Operation Inspection and Setup

1. The Production Supervisor verifies that the previous batch record is closed and that the equipment cleaning log indicates the BPM-01 is clean and ready for use.
2. The QC Inspector inspects the cleaned blister packaging machine (BPM-01) to ensure it is free from any residual product or cleaning agents and that all parts are properly assembled according to the BPM-01 Operation Manual.
3. The Production Supervisor verifies that the appropriate packaging materials (e.g., blister film, lidding foil) have been approved for use by the QC Inspector and are available at the packaging area.

4. The Production Supervisor ensures that all necessary documentation, including the Batch Packaging Record (BPR), Equipment Usage Log, and cleaning log, are available and properly filled out with required information.
5. The operator puts on the appropriate PPE, including safety glasses, disposable gloves, dust mask, hairnet, cleanroom gown/lab coat, and shoe covers.
6. The operator installs the appropriate tooling (e.g., forming dies, sealing dies, cutting dies) for the specific product and blister configuration, following the BPM-01 Operation Manual.
7. The operator adjusts the machine settings, including temperature, pressure, and speed, according to the parameters specified in the Batch Packaging Record (BPR) and the BPM-01 Operation Manual.
8. The operator performs a dry run of the blister packaging machine (BPM-01) without product to verify proper operation and alignment of the tooling.
9. The Production Supervisor and QC Inspector inspect the test blisters produced during the dry run to ensure that they meet the required quality standards, including proper forming, sealing, and cutting. Adjustments are made as necessary.
10. The operator documents all pre-operation inspection and setup activities in the Equipment Usage Log and Batch Packaging Record (BPR).

5.2 Operation of the Blister Packaging Machine

1. The operator loads the product into the hopper or feeding system of the blister packaging machine (BPM-01), ensuring that the product is free from any foreign matter or contamination.
2. The operator starts the BPM-01 and monitors the packaging process to ensure that the product is being properly filled into the blisters, sealed with the lidding foil, and cut into individual units.
3. The QC Inspector performs in-process quality checks at regular intervals, as defined in the Batch Packaging Record (BPR), to verify seal integrity, correct printing, proper product placement in blisters, and overall appearance of the finished blisters.
4. The QC Inspector records all inspection results in the Batch Packaging Record (BPR).
5. The operator makes adjustments to the machine settings as needed to maintain the quality of the finished blisters, under the supervision of the Production Supervisor.
6. The operator monitors the machine for any malfunctions or unusual noises and reports any issues to the Production Supervisor immediately.
7. The Production Supervisor investigates any malfunctions or unusual noises and takes corrective action as necessary, documenting all actions taken in the Deviation Report Form.
8. The operator collects samples of the finished blisters at regular intervals for retention and stability testing, as specified in the Batch Packaging Record (BPR).
9. The operator documents all operational activities in the Equipment Usage Log and Batch Packaging Record (BPR), including any adjustments made to the machine settings, quality control checks performed, and any deviations encountered.

5.3 Cleaning of the Blister Packaging Machine

1. The operator puts on the appropriate PPE, including safety glasses, disposable gloves, dust mask, hairnet, cleanroom gown/lab coat, and shoe covers.
2. The operator shuts down the blister packaging machine (BPM-01) and disconnects it from the power supply.
3. The operator removes any remaining product and packaging materials from the machine and the surrounding area.
4. The operator uses a vacuum cleaner with a HEPA filter to remove any loose dust or debris from the machine.
5. The operator disassembles the machine according to the BPM-01 Operation Manual, separating the parts that need to be cleaned.
6. The operator cleans all accessible surfaces of the machine, including the tooling, hopper, and conveyor belt, with a lint-free wipe dampened with the approved cleaning solution (e.g., 70% Isopropyl Alcohol). Refer to the approved cleaning validation protocol for specific cleaning agents and procedures.
7. The operator pays particular attention to cleaning areas that come into direct contact with the product.
8. The operator rinses all cleaned parts with purified water and dries them with a lint-free wipe.
9. The operator reassembles the machine according to the BPM-01 Operation Manual.
10. The QC Inspector inspects the cleaned machine to ensure that it is free from any residual product or cleaning agents.
11. The operator documents the cleaning process in the Blister Packaging Machine (BPM-01) Cleaning Log, including the date, time, cleaning agent used, and the initials of the person who performed the cleaning.
12. The Production Supervisor verifies the completion of the cleaning process and signs the Blister Packaging Machine (BPM-01) Cleaning Log.

5.4 Preventative Maintenance of the Blister Packaging Machine

1. The Production Supervisor schedules routine preventative maintenance activities according to the Preventative Maintenance Schedule and the BPM-01 Operation Manual.
2. The operator puts on the appropriate PPE, including safety glasses, disposable gloves, and safety shoes.
3. The operator shuts down the blister packaging machine (BPM-01) and disconnects it from the power supply.
4. The operator inspects the machine for any signs of wear or damage, including loose bolts, worn belts, and damaged wires.
5. The operator lubricates all moving parts of the machine according to the BPM-01 Operation Manual, using the approved lubricant.
6. The operator tightens any loose bolts or screws using a calibrated torque wrench (TRQ-01) to the specified torque.
7. The operator replaces any worn or damaged parts, such as belts, bearings, and seals, according to the BPM-01 Operation Manual.

8. The operator calibrates the temperature controllers and other critical instruments according to the calibration schedule.
9. The operator tests the machine to ensure that it is operating properly.
10. The operator documents all maintenance activities in the Blister Packaging Machine (BPM-01) Maintenance Log, including the date, time, the tasks performed, the parts replaced, and the initials of the person who performed the maintenance.
11. The Production Supervisor verifies the completion of the maintenance process and signs the Blister Packaging Machine (BPM-01) Maintenance Log.

6.0 POST-PACKAGING ACTIVITIES

1. The operator ensures that all finished blisters are properly labeled and packaged according to the Batch Packaging Record (BPR).
2. The operator removes all remaining packaging materials and product from the packaging area.
3. The operator cleans the packaging area according to the approved cleaning procedure.
4. The Production Supervisor verifies that all packaging materials and product have been properly accounted for and that the packaging area is clean and ready for the next batch.
5. The Production Supervisor reconciles all packaging materials and product against the Batch Packaging Record (BPR) and investigates any discrepancies.
6. The QC Inspector reviews the Batch Packaging Record (BPR) and all associated documentation to ensure that all activities have been properly documented and that the finished blisters meet the required quality standards.
7. The QA Manager reviews and approves the Batch Packaging Record (BPR) before the finished blisters are released for distribution.

7.0 SAFETY PRECAUTIONS

- Always wear the appropriate PPE, including safety glasses, disposable gloves, dust mask, hairnet, cleanroom gown/lab coat, and shoe covers, when operating, cleaning, or maintaining the blister packaging machine (BPM-01).
- Ensure that the machine is properly grounded to prevent electrical shock.
- Never operate the machine without all safety guards and interlocks in place.
- Do not reach into the machine while it is in operation.
- Use caution when handling cleaning agents and lubricants. Refer to the Material Safety Data Sheets (MSDS) for specific safety information.
- Disconnect the machine from the power supply before performing any cleaning or maintenance activities.
- Use calibrated tools and equipment for all maintenance activities.
- Report any unsafe conditions or practices to the Production Supervisor immediately.

- Follow all lockout/tagout procedures before performing any maintenance on the machine.
- Ensure adequate ventilation when using cleaning agents.
- Be aware of pinch points and moving parts during operation.
- Properly dispose of used cleaning materials and packaging waste.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date:

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Document Control Information

Document ID: SOP-PKG-001

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System