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Title:	Operation, Cleaning, and Maintenance of the Mechanical Sifter	**Version:**	1.0
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Operation, Cleaning, and Maintenance of the Mechanical Sifter

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure outlines the standardized method for the operation, cleaning, and maintenance of the mechanical sifter (SFT-02) at NovaThera Pharmaceuticals to ensure proper sieving, prevent cross-contamination, and maintain equipment functionality in pharmaceutical manufacturing. This SOP ensures compliance with Good Manufacturing Practices (GMP) and regulatory requirements.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to all personnel involved in the operation, cleaning, and maintenance of the mechanical sifter (SFT-02) used in the manufacturing of pharmaceutical products at NovaThera Pharmaceuticals Pvt. Ltd. This SOP covers all materials and products sieved using this equipment.

3.0 RESPONSIBILITY

QC Inspector: Performs pre-use inspection of the sifter, collects samples for post-cleaning verification, and reviews cleaning and maintenance records.

Production Supervisor: Oversees the operation of the sifter, ensures adherence to this SOP, and addresses any operational issues.

QA Manager: Reviews and approves the SOP, monitors compliance, and investigates deviations related to the sifter.

Head of QA: Approves the SOP and ensures its implementation and effectiveness.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, dust mask, gloves (appropriate for handling the materials being sieved), ear protection (if noise levels exceed acceptable limits), dedicated clean room gown.

Equipment: Mechanical Sifter (SFT-02), calibrated weighing balance, cleaning agents (e.g., isopropyl alcohol, deionized water, validated detergent), lint-free cloths, vacuum cleaner with HEPA filter, calibrated timer, maintenance tools (as specified in the equipment manual).

Documentation: Equipment logbook, cleaning log, maintenance log, deviation report form, material traceability records.

5.0 PROCEDURE

5.1 Pre-Operation Inspection

1. The Production Supervisor shall verify that the sifter (SFT-02) is clean and that the cleaning log has been reviewed and signed off by the QC Inspector.

2. The Production Supervisor shall verify that the maintenance log has been reviewed for any outstanding maintenance issues.

3. The QC Inspector shall visually inspect the sifter (SFT-02) for cleanliness, paying particular attention to the sieve mesh, seals, and product contact surfaces. Record the inspection in the equipment logbook.

4. The QC Inspector shall inspect the sieve mesh for any damage (e.g., tears, holes, or deformation). If damage is found, the sifter shall not be used and a deviation report shall be initiated.

5. The Production Supervisor shall ensure that the correct sieve mesh size is installed according to the batch manufacturing record (BMR).

6. The Production Supervisor shall verify that all safety guards and interlocks are in place and functioning correctly.

7. The Production Supervisor shall ensure that the area around the sifter is clean and free of obstructions.

5.2 Operation of the Mechanical Sifter

1. The Production Supervisor shall verify that the sifter is positioned correctly and securely on a stable surface.

2. The Production Supervisor shall wear the required PPE as specified in Section 4.0.

3. The Production Supervisor shall slowly and carefully load the material to be sieved into the sifter hopper, ensuring not to exceed the maximum capacity specified in the equipment manual.

4. The Production Supervisor shall start the sifter according to the manufacturer's instructions.

5. The Production Supervisor shall monitor the sifting process, ensuring that the material is flowing smoothly and that there are no blockages.

6. The Production Supervisor shall adjust the sifter speed and amplitude (if adjustable) as necessary to optimize the sifting process.

7. The Production Supervisor shall collect the sieved material from the designated collection container.

8. The Production Supervisor shall ensure that all material is completely sieved before stopping the sifter.

9. The Production Supervisor shall stop the sifter according to the manufacturer's instructions.

10. The Production Supervisor shall carefully remove the collection container containing the sieved material.

11. The Production Supervisor shall weigh the sieved material and record the weight in the batch record.

12. The Production Supervisor shall collect any oversized material remaining on the sieve and weigh it. Record the weight in the batch record.

13. The Production Supervisor shall ensure all material traceability records are updated according to GMP guidelines.

14. The Production Supervisor shall document any deviations or unusual occurrences during the sifting process in the equipment logbook and initiate a deviation report if necessary.

5.3 Cleaning of the Mechanical Sifter

1. The Production Supervisor shall disconnect the sifter from the power supply.

2. The Production Supervisor shall wear the required PPE as specified in Section 4.0.

3. The Production Supervisor shall remove any remaining material from the sifter hopper and collection container. Dispose of the material according to the appropriate waste disposal procedure.

4. The Production Supervisor shall disassemble the sifter according to the manufacturer's instructions.

5. The Production Supervisor shall thoroughly vacuum all accessible surfaces of the sifter, including the sieve mesh, using a vacuum cleaner with a HEPA filter.

6. The Production Supervisor shall wash all product contact parts (e.g., sieve mesh, hopper, collection container) with a validated detergent solution, ensuring all surfaces are thoroughly cleaned.

7. The Production Supervisor shall rinse all product contact parts with deionized water until all traces of detergent are removed.

8. The Production Supervisor shall sanitize all product contact parts with isopropyl alcohol (70% v/v).

9. The Production Supervisor shall allow all parts to air dry completely before reassembling the sifter.

10. The Production Supervisor shall reassemble the sifter according to the manufacturer's instructions.

11. The Production Supervisor shall visually inspect the reassembled sifter for cleanliness.

12. The QC Inspector shall collect swab samples from representative product contact surfaces to verify the effectiveness of the cleaning procedure. Submit the samples to the QC laboratory for analysis.

13. The QC Inspector shall review the analytical results. If the results are within the acceptable limits, the QC Inspector shall sign off the cleaning log.

14. The Production Supervisor shall record the cleaning procedure in the cleaning log, including the date, time, cleaning agent used, and the initials of the person performing the cleaning.

5.4 Maintenance of the Mechanical Sifter

1. The Production Supervisor shall ensure that the sifter is maintained according to the manufacturer's recommended maintenance schedule.

2. The Production Supervisor shall schedule periodic maintenance activities, such as lubrication of moving parts, inspection of belts and bearings, and calibration of timers.

3. The Production Supervisor shall document all maintenance activities in the maintenance log, including the date, time, description of the work performed, and the initials of the person performing the maintenance.

4. The Production Supervisor shall use only approved spare parts for maintenance and repairs.

5. The Production Supervisor shall ensure that any repairs are performed by qualified personnel.

6. The Production Supervisor shall after any maintenance or repair, perform a functional test of the sifter to ensure that it is operating correctly.

7. The Production Supervisor shall recalibrate the timer and other measuring devices according to the established calibration schedule.

8. The QC Inspector shall verify the calibration status of the timer and other measuring devices.

9. The Production Supervisor shall record any deviations or unusual occurrences during the maintenance process in the equipment logbook and initiate a deviation report if necessary.

6.0 POST-OPERATION ACTIVITIES

1. The Production Supervisor shall ensure that all sieved material is properly labeled and stored according to the appropriate storage conditions.

2. The Production Supervisor shall return all equipment and materials used during the sifting process to their designated storage locations.

3. The Production Supervisor shall ensure that the work area is clean and free of debris.

4. The Production Supervisor shall review the batch record to ensure that all required information has been recorded.

5. The Production Supervisor shall notify the QC Inspector that the sifter is ready for cleaning verification.

7.0 SAFETY PRECAUTIONS

1. Always wear appropriate PPE, including safety glasses, dust mask, and gloves, when operating, cleaning, or maintaining the sifter.

2. Ensure that the sifter is properly grounded to prevent electrical shock.

3. Never operate the sifter with the safety guards removed.

4. Do not exceed the maximum capacity of the sifter.

5. Use caution when handling cleaning agents and solvents. Follow the manufacturer's instructions and wear appropriate PPE.

6. Do not use compressed air to clean the sifter, as this may create airborne dust particles.

7. Ensure that the sifter is disconnected from the power supply before performing any maintenance or repairs.

8. If noise levels exceed acceptable limits, wear ear protection.

9. Report any unsafe conditions or equipment malfunctions to the Production Supervisor immediately.

10. Refer to the Material Safety Data Sheets (MSDS) for all chemicals used in the cleaning process.

11. Ensure proper ventilation during cleaning and operation to minimize exposure to dust.

8.0 APPROVALS

Prepared By: Production Supervisor

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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