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Title:	Operation, Cleaning, and Maintenance of the Tablet Compression Machine	Version:	1.0
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Operation, Cleaning, and Maintenance of the Tablet Compression Machine

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure outlines the standard operating procedures for the safe and efficient operation, cleaning, and maintenance of the tablet compression machine (TCP-01) within NovaThera Pharmaceuticals' pharmaceutical manufacturing environment. This SOP ensures consistent tablet quality, operator safety, and equipment longevity, adhering to Good Manufacturing Practices (GMP) and relevant regulatory guidelines.

2.0 SCOPE

This SOP applies to all personnel involved in the operation, cleaning, and maintenance of the tablet compression machine (TCP-01) used for the compression of tablets at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This includes, but is not limited to, the manufacturing of all applicable pharmaceutical products and batches processed on the TCP-01 equipment. This SOP covers pre-operation checks, operational procedures, in-process monitoring, post-operation cleaning, and routine maintenance activities. It excludes major repairs requiring specialized technicians not routinely assigned to the Production Department.

3.0 RESPONSIBILITY

QC Inspector:

- Performs pre-operation checks on the tablet compression machine (TCP-01) to ensure cleanliness and proper setup.
- Conducts in-process quality control checks during tablet compression, including tablet weight, hardness, thickness, and friability testing, according to established control limits.
- Documents all inspection results in the designated batch records and equipment logbooks.
- Reports any deviations or out-of-specification results to the Production Supervisor immediately.

Production Supervisor:

- Oversees the operation of the tablet compression machine (TCP-01) and ensures adherence to this SOP.
- Provides training to operators on the proper operation, cleaning, and maintenance of the TCP-01 equipment.
- Ensures that all required documentation is completed accurately and in a timely manner.
- Investigates and resolves any issues or deviations that may arise during tablet compression.
- Schedules and coordinates routine maintenance activities for the tablet compression machine (TCP-01).
- Ensures that the work area is clean and organized.

QA Manager:

- Reviews and approves this SOP and any revisions thereto.
- Ensures that the SOP is implemented and followed correctly.
- Audits the tablet compression process to ensure compliance with GMP and regulatory requirements.
- Reviews and approves batch records and equipment logbooks.
- Investigates and resolves any quality-related issues that may arise during tablet compression.

Head of QA:

- Provides final approval for this SOP and any revisions thereto.
- Oversees the quality assurance program for tablet manufacturing.
- Ensures that the company complies with all applicable GMP and regulatory requirements.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Dust mask or respirator (N95 or equivalent)

- Disposable gloves (nitrile or latex)
- Dedicated manufacturing gown/overalls
- Dedicated manufacturing shoes or shoe covers
- Hearing protection (earplugs or earmuffs)

Equipment:

- Tablet Compression Machine (TCP-01)
- Vacuum cleaner with HEPA filter
- Cleaning cloths (lint-free)
- Cleaning solutions (e.g., 70% isopropyl alcohol, validated detergent)
- Calibrated weighing balance
- Calibrated hardness tester
- Calibrated thickness tester
- Friability tester
- Tablet counter
- De-dusting unit
- Inspection lamp
- Torque wrench
- Tool kit (designated for TCP-01)
- Equipment logbook (TCP-01-LOG)

Documentation:

- Batch Manufacturing Record (BMR)
- Equipment Logbook (TCP-01-LOG)
- Cleaning Log (CLN-003)
- Maintenance Schedule (MNT-SCH-002)
- Deviation Report Form (DEV-001)
- SOP Training Record (TRN-REC-005)

5.0 PROCEDURE

5.1 Pre-Operation Checks and Setup

1. The Production Supervisor verifies that the tablet compression machine (TCP-01) has been properly cleaned and sanitized according to SOP CLN-003 and the cleaning log is complete.
2. The QC Inspector performs a visual inspection of the TCP-01 to ensure it is free from any residual powder, debris, or damage. Any discrepancies are documented in the equipment logbook

(TCP-01-LOG) and reported to the Production Supervisor. Production will not proceed until issues are resolved and documented.

3. The Production Supervisor confirms that the correct punches and dies for the specific tablet being manufactured are installed in the TCP-01.
4. The Production Supervisor verifies that the hopper is clean and securely attached to the TCP-01.
5. The Production Supervisor ensures that the discharge chute and tablet collection container are clean and properly positioned.
6. The Production Supervisor confirms that the power supply and emergency stop buttons are functional.
7. The Production Supervisor reviews the Batch Manufacturing Record (BMR) to verify the tablet weight, hardness, thickness, and friability specifications.
8. The Production Supervisor sets the initial compression parameters on the TCP-01 control panel according to the BMR.
9. The Production Supervisor verifies that the de-dusting unit is connected and functioning correctly.
10. The QC Inspector calibrates the weighing balance, hardness tester, and thickness tester according to their respective calibration SOPs. Calibration records must be available for review.
11. The Production Supervisor ensures that sufficient quantities of the tablet blend are available for compression. The material must be within its expiry/retest date.

5.2 Machine Operation

1. The Production Supervisor initiates the TCP-01 operation by pressing the start button.
2. The operator observes the initial tablets produced, ensuring that the tablet weight, hardness, thickness, and appearance are within acceptable limits.
3. The QC Inspector collects samples of tablets at regular intervals (e.g., every 15 minutes or as specified in the BMR) for in-process quality control testing.
4. The QC Inspector performs tablet weight, hardness, thickness, and friability testing according to the BMR specifications. Results are documented immediately in the BMR.
5. The Production Supervisor adjusts the compression parameters on the TCP-01 as needed to maintain tablet quality within the specified limits. All adjustments are documented in the BMR.
6. The Production Supervisor monitors the tablet collection container, ensuring that it is emptied regularly to prevent overfilling.
7. The operator monitors the TCP-01 for any unusual noises, vibrations, or malfunctions. Any issues are reported to the Production Supervisor immediately.
8. If the TCP-01 stops unexpectedly, the Production Supervisor investigates the cause and takes corrective action. The incident is documented in the equipment logbook (TCP-01-LOG) and a deviation report is initiated if necessary.
9. The QC Inspector verifies the performance of the de-dusting unit to ensure that tablets are free from excess powder.

5.3 Addressing Common Operational Issues

- **Tablet Capping/Lamination:** If tablet capping or lamination occurs, the Production Supervisor will: 1) Reduce the compression force gradually. 2) Ensure proper lubrication of the die wall with magnesium stearate. 3) Reduce machine speed to allow for proper air expulsion. 4) Check the blend for excessive fines and segregation. Record adjustments and observations in the BMR.
- **Tablet Sticking:** If tablet sticking occurs, the Production Supervisor will: 1) Ensure adequate lubrication of the punches and dies. 2) Reduce the moisture content of the granulation. 3) Adjust the compression force. 4) Clean the punch faces more frequently. Record adjustments and observations in the BMR.
- **Weight Variation:** If weight variation exceeds the acceptable limits, the Production Supervisor will: 1) Check the feed frame and ensure proper flow of the blend. 2) Inspect the dies for wear or damage. 3) Adjust the fill depth. Record adjustments and observations in the BMR.

5.4 End of Production Run

1. The Production Supervisor stops the TCP-01 operation when the required number of tablets has been compressed, as specified in the BMR.
2. The operator removes any remaining tablet blend from the hopper and stores it according to the BMR instructions.
3. The operator collects all tablets from the collection container and transfers them to a properly labeled container for further processing (e.g., coating, packaging).
4. The Production Supervisor reconciles the amount of tablet blend used with the number of tablets produced, according to the BMR requirements. Any discrepancies are investigated and documented.
5. The Production Supervisor completes all required sections of the BMR, including the start and end times, tablet weight, hardness, thickness, and friability results, and any deviations or issues that occurred during the compression process.

5.5 Cleaning Procedure

1. The operator dons appropriate PPE (safety glasses, dust mask, gloves, gown, and shoe covers).
2. The operator turns off the TCP-01 and disconnects it from the power supply.
3. The operator removes the punches and dies from the TCP-01.
4. The operator uses a vacuum cleaner with a HEPA filter to remove any loose powder from the TCP-01 surfaces.
5. The operator wipes all accessible surfaces of the TCP-01 with a clean, lint-free cloth dampened with 70% isopropyl alcohol or validated detergent.
6. The operator cleans the punches and dies with a validated cleaning solution and dries them thoroughly.
7. The operator reassembles the TCP-01, ensuring that all parts are properly installed and secured.
8. The operator wipes down the exterior of the TCP-01 with a clean, lint-free cloth dampened with 70% isopropyl alcohol or validated detergent.
9. The operator cleans the surrounding work area, removing any spilled powder or debris.

10. The Production Supervisor inspects the TCP-01 to ensure that it has been properly cleaned.
11. The operator records the cleaning procedure in the cleaning log (CLN-003), including the date, time, and initials of the person who performed the cleaning.

5.6 Preventative Maintenance

1. The Production Supervisor schedules preventative maintenance for the TCP-01 according to the maintenance schedule (MNT-SCH-002).
2. Qualified maintenance personnel perform the scheduled maintenance tasks, which may include:
 - Lubricating moving parts.
 - Tightening loose bolts and screws.
 - Replacing worn or damaged parts.
 - Inspecting electrical connections.
 - Calibrating the compression force.
3. Maintenance personnel document all maintenance activities in the equipment logbook (TCP-01-LOG), including the date, time, and description of the work performed.
4. The Production Supervisor reviews the equipment logbook (TCP-01-LOG) to ensure that all scheduled maintenance has been completed.

6.0 POST-OPERATION ACTIVITIES

Following completion of the tablet compression run and equipment cleaning:

1. The Production Supervisor reviews the completed Batch Manufacturing Record (BMR) for accuracy and completeness.
2. The QC Inspector verifies that all in-process quality control results meet the BMR specifications.
3. The Production Supervisor stores the punches and dies in a designated location, protected from damage and contamination.
4. The QA Manager reviews the BMR and equipment logbook (TCP-01-LOG) for any deviations or issues that occurred during the compression process.
5. The Head of QA approves the BMR and releases the tablets for further processing (e.g., coating, packaging).

7.0 SAFETY PRECAUTIONS

1. All personnel operating or maintaining the tablet compression machine (TCP-01) must be properly trained on its safe operation and potential hazards.
2. Always wear appropriate PPE (safety glasses, dust mask, gloves, gown, and shoe covers) when operating or cleaning the TCP-01.
3. Never operate the TCP-01 without the safety guards in place.

4. Use caution when handling punches and dies, as they can be sharp and heavy.
5. Disconnect the TCP-01 from the power supply before performing any maintenance or cleaning.
6. Use only approved cleaning solutions and solvents.
7. Ensure adequate ventilation when cleaning with solvents.
8. Do not operate the TCP-01 if it is malfunctioning or damaged. Report any issues to the Production Supervisor immediately.
9. Follow lockout/tagout procedures when performing maintenance on the TCP-01.
10. In case of an emergency, use the emergency stop button to immediately shut down the TCP-01.
11. Be aware of the location of the nearest fire extinguisher and emergency exits.
12. Material Safety Data Sheets (MSDS) for all chemicals used must be readily available.
13. Proper housekeeping must be maintained in the work area to prevent slips, trips, and falls.
14. Hearing protection is required when operating the TCP-01 for extended periods.
15. Report any near misses or incidents to the Production Supervisor immediately.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date:

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