Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-PROD-007
Title:	In-Process Quality Control (IPQC) Checks for Tablet Compression	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

In-Process Quality Control (IPQC) Checks for Tablet Compression

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure defines the standardized methodology for performing In-Process Quality Control (IPQC) checks during tablet compression operations in pharmaceutical manufacturing at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures adherence to Good Manufacturing Practices (GMP) and facilitates the production of tablets that meet established quality standards. It provides clear instructions to personnel responsible for monitoring and evaluating the quality of tablet compression processes, preventing deviations, and ensuring consistent product quality.

2.0 SCOPE

This SOP applies to all tablet compression operations conducted at NovaThera Pharmaceuticals Pvt. Ltd. This includes all batches and products manufactured using tablet compression processes. The procedure outlines the required IPQC checks during the tablet compression stage, including tablet weight, thickness, hardness, friability, disintegration, and appearance, irrespective of the specific formulation or batch size. It covers all personnel involved in the tablet compression process, including operators, supervisors, and quality control personnel. This SOP excludes pre-compression IPQC checks (e.g., blend uniformity) and post-compression activities like packaging.

3.0 RESPONSIBILITY

QC Inspector:

- Performs IPQC checks as per this SOP.
- Documents all observations and results accurately in the designated forms and registers.
- Reports any deviations or out-of-specification (OOS) results to the Production Supervisor immediately.
- Ensures that all measuring instruments are calibrated and in good working condition prior to use.
- Maintains a clean and organized work area during IPQC checks.

Production Supervisor:

- Ensures that all personnel are trained on this SOP and adhere to its requirements.
- Oversees the tablet compression process and verifies that IPQC checks are performed at the specified intervals.
- Investigates any deviations or OOS results reported by the QC Inspector and implements corrective actions.
- Ensures that all equipment used in tablet compression is properly maintained and calibrated.
- Reviews and approves IPQC records.

QA Manager:

- Reviews and approves this SOP.
- Provides oversight of the IPQC program.
- Ensures that the IPQC program complies with GMP regulations.
- Investigates any major deviations or OOS results and ensures that appropriate corrective and preventive actions (CAPA) are implemented.
- Conducts periodic audits of the tablet compression process and IPQC activities to ensure compliance with this SOP and GMP regulations.

Head of QA:

- Approves this SOP and any revisions.
- Provides final oversight of the IPQC program.
- Ensures that adequate resources are available to support the IPQC program.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety Glasses
- Dust Mask
- Gloves (Nitrile)

- Lab Coat

Equipment:

- Tablet Weight Balance (accurate to 0.1 mg, Code: WBL-01)
- Tablet Thickness Tester (digital caliper, Code: TTT-01)
- Tablet Hardness Tester (Erweka TBH Series, Code: HTS-02)
- Friabilator (Roche type, Code: FRI-01)
- Disintegration Tester (USP compliant, Code: DST-01)
- Vernier Caliper
- Visual Inspection Station with appropriate lighting

Documentation:

- Tablet Compression Record (Form No: NT-PROD-007-01)
- IPQC Check Sheet (Form No: NT-QA-007-02)
- Deviation Report Form (Form No: NT-QA-001-01)
- Equipment Calibration Log Book (Form No: NT-ENG-001-01)
- Cleaning Log Book (Form No: NT-CLEAN-001-01)

5.0 PROCEDURE

5.1 Preparation for IPQC Checks

1. The QC Inspector reviews the Tablet Compression Record (Form No: NT-PROD-007-01) to understand the batch details, target specifications, and sampling schedule.

2. The QC Inspector verifies that the equipment to be used for IPQC checks (Tablet Weight Balance (WBL-01), Tablet Thickness Tester (TTT-01), Tablet Hardness Tester (HTS-02), Friabilator (FRI-01), Disintegration Tester (DST-01), Vernier Caliper) is calibrated and within the calibration due date by checking the Equipment Calibration Log Book (Form No: NT-ENG-001-01).

3. The QC Inspector ensures that the work area is clean and free from any extraneous materials. This should be documented in the Cleaning Log Book (Form No: NT-CLEAN-001-01).

4. The QC Inspector dons the required PPE (Safety Glasses, Dust Mask, Gloves (Nitrile), Lab Coat).

5. The QC Inspector retrieves the IPQC Check Sheet (Form No: NT-QA-007-02) and fills in the necessary information, including the batch number, product name, date, and time.

5.2 Tablet Weight Check

1. The QC Inspector randomly selects a sample of 10 tablets from the compression machine at predetermined intervals (e.g., every 30 minutes or as specified in the Tablet Compression Record). The sampling frequency must be justified and documented within the batch record.

2. Using the Tablet Weight Balance (WBL-01), the QC Inspector individually weighs each tablet and records the weight on the IPQC Check Sheet (Form No: NT-QA-007-02). Ensure the balance is tared before each weighing.

3. The QC Inspector calculates the average weight of the 10 tablets and records it on the IPQC Check Sheet (Form No: NT-QA-007-02).

4. The QC Inspector compares the individual tablet weights and the average weight to the pre-defined specifications outlined in the Tablet Compression Record (Form No: NT-PROD-007-01).

5. If any individual tablet weight or the average weight is outside the specified limits, the QC Inspector immediately informs the Production Supervisor. This is considered a deviation.

5.3 Tablet Thickness Check

1. The QC Inspector randomly selects a sample of 10 tablets from the compression machine at the same intervals as the weight check.

2. Using the Tablet Thickness Tester (TTT-01), the QC Inspector measures the thickness of each tablet and records the measurement on the IPQC Check Sheet (Form No: NT-QA-007-02).

3. The QC Inspector calculates the average thickness of the 10 tablets and records it on the IPQC Check Sheet (Form No: NT-QA-007-02).

4. The QC Inspector compares the individual tablet thicknesses and the average thickness to the pre-defined specifications outlined in the Tablet Compression Record (Form No: NT-PROD-007-01).

5. If any individual tablet thickness or the average thickness is outside the specified limits, the QC Inspector immediately informs the Production Supervisor. This is considered a deviation.

5.4 Tablet Hardness Check

1. The QC Inspector randomly selects a sample of 10 tablets from the compression machine at the same intervals as the weight and thickness checks.

2. Using the Tablet Hardness Tester (HTS-02), the QC Inspector measures the hardness of each tablet and records the measurement on the IPQC Check Sheet (Form No: NT-QA-007-02). Ensure the tablet is placed correctly on the tester.

3. The QC Inspector calculates the average hardness of the 10 tablets and records it on the IPQC Check Sheet (Form No: NT-QA-007-02).

4. The QC Inspector compares the individual tablet hardness values and the average hardness to the pre-defined specifications outlined in the Tablet Compression Record (Form No: NT-PROD-007-01).

5. If any individual tablet hardness value or the average hardness is outside the specified limits, the QC Inspector immediately informs the Production Supervisor. This is considered a deviation.

5.5 Tablet Friability Check

1. The QC Inspector randomly selects a sample of 20 tablets from the compression machine at the same intervals as the previous checks.

2. The QC Inspector carefully removes any loose dust from the tablets.

3. The QC Inspector accurately weighs the 20 tablets together using the Tablet Weight Balance (WBL-01) and records the initial weight (W1) on the IPQC Check Sheet (Form No: NT-QA-007-02).

4. The QC Inspector places the 20 tablets in the Friabilator (FRI-01) and runs the friabilator for 100 revolutions at 25 rpm.

5. After 100 revolutions, the QC Inspector removes the tablets from the friabilator and carefully removes any loose dust.

6. The QC Inspector accurately weighs the 20 tablets together again using the Tablet Weight Balance (WBL-01) and records the final weight (W2) on the IPQC Check Sheet (Form No: NT-QA-007-02).

7. The QC Inspector calculates the percentage weight loss (friability) using the following formula: % Friability = [(W1 – W2) / W1] x 100.

8. The QC Inspector records the calculated friability percentage on the IPQC Check Sheet (Form No: NT-QA-007-02).

9. The QC Inspector compares the friability percentage to the pre-defined specifications outlined in the Tablet Compression Record (Form No: NT-PROD-007-01).

10. If the friability percentage is outside the specified limits, the QC Inspector immediately informs the Production Supervisor. This is considered a deviation.

5.6 Tablet Disintegration Check

1. The QC Inspector randomly selects a sample of 6 tablets from the compression machine at the same intervals as the previous checks.

2. The QC Inspector places one tablet in each of the six tubes of the Disintegration Tester (DST-01).

3. The QC Inspector lowers the basket rack assembly into the disintegration media (as specified in the product master formula – typically water or 0.1N HCl) maintained at 37 ± 2°C.

4. The QC Inspector starts the disintegration tester and observes the tablets.

5. The QC Inspector records the time it takes for each tablet to completely disintegrate, with no discernible core remaining, on the IPQC Check Sheet (Form No: NT-QA-007-02).

6. The QC Inspector compares the disintegration time for each tablet to the pre-defined specifications outlined in the Tablet Compression Record (Form No: NT-PROD-007-01).

7. If any tablet fails to disintegrate within the specified time limit, the QC Inspector immediately informs the Production Supervisor. This is considered a deviation.

5.7 Visual Inspection

1. The QC Inspector continuously performs visual inspection of the tablets during the compression process.

2. The QC Inspector observes the tablets for any visual defects, such as capping, lamination, chipping, cracks, mottling, or imperfections in the tablet surface.

3. The QC Inspector records any observed visual defects on the IPQC Check Sheet (Form No: NT-QA-007-02).

4. If any significant visual defects are observed, the QC Inspector immediately informs the Production Supervisor. This is considered a deviation. Note if a large number of tablets are defective this requires immediate attention.

5. The QC Inspector assesses the colour and embossing/engraving on the tablets, comparing them to the approved reference standard.

5.8 Deviation Handling

1. If any deviation from the specified limits is observed during any of the IPQC checks, the QC Inspector immediately informs the Production Supervisor.

2. The Production Supervisor investigates the deviation to determine the root cause.

3. The Production Supervisor initiates a Deviation Report Form (Form No: NT-QA-001-01) and documents the details of the deviation, the investigation findings, and the corrective actions taken.

4. The QA Manager reviews and approves the Deviation Report Form (Form No: NT-QA-001-01) and ensures that appropriate corrective and preventive actions (CAPA) are implemented to prevent recurrence of the deviation.

5. Defective tablets should be quarantined and disposed of according to SOP-MAT-012.

6.0 POST-COMPRESSION ACTIVITIES

1. The QC Inspector reviews the completed IPQC Check Sheet (Form No: NT-QA-007-02) to ensure that all data is accurately recorded and complete.

2. The QC Inspector submits the completed IPQC Check Sheet (Form No: NT-QA-007-02) and any associated Deviation Report Forms (Form No: NT-QA-001-01) to the Production Supervisor for review and approval.

3. The Production Supervisor reviews the IPQC Check Sheet (Form No: NT-QA-007-02) and Deviation Report Forms (Form No: NT-QA-001-01) to verify that all IPQC checks were performed according to this SOP and that any deviations were appropriately investigated and resolved.

4. The Production Supervisor approves the IPQC Check Sheet (Form No: NT-QA-007-02) and Deviation Report Forms (Form No: NT-QA-001-01) and forwards them to the QA department for final review and archiving.

5. The QA department reviews the IPQC documentation and ensures that all records are complete and compliant with GMP regulations.

6. All IPQC records are archived according to the company's record retention policy.

7. The QC Inspector ensures the work area and equipment are cleaned after the IPQC checks are complete.

7.0 SAFETY PRECAUTIONS

1. Always wear the required PPE (Safety Glasses, Dust Mask, Gloves (Nitrile), Lab Coat) when performing IPQC checks.

2. Handle tablets carefully to avoid damage or contamination.

3. Use caution when operating the Tablet Hardness Tester (HTS-02), Friabilator (FRI-01), and Disintegration Tester (DST-01) to avoid injury.

4. Ensure that all electrical equipment is properly grounded and maintained.

5. Report any unsafe conditions or potential hazards to the Production Supervisor immediately.

6. Avoid generating excessive dust during handling of the tablets.

7. Refer to the Material Safety Data Sheets (MSDS) for any chemicals used during the disintegration testing.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Document Approval

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

Document Control Information

Document ID: SOP-PROD-007

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System