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Operation, Cleaning, and Maintenance of the Bottle Filling and Capping Line

Category: Packaging

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure defines the standardized process for the proper operation, cleaning, and maintenance of the bottle filling and capping line (BFC-01) within the packaging department at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, ensuring compliance with Good Manufacturing Practices (GMP) and contributing to the consistent quality of pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all personnel involved in the operation, cleaning, and maintenance of the bottle filling and capping line (BFC-01) utilized for packaging of liquid and solid oral dosage forms at NovaThera Pharmaceuticals Pvt. Ltd. This includes, but is not limited to, all bottle sizes and closure types processed on the line. The procedure covers pre-operation checks, operational steps, cleaning procedures, preventative maintenance, and documentation requirements.

3.0 RESPONSIBILITY

QC Inspector:

- Verify the cleanliness of the bottle filling and capping line (BFC-01) before operation.
- Perform in-process quality checks during operation according to approved quality control procedures.
- Document all quality control checks and observations in the designated logbooks and forms.
- Quarantine any product or material suspected of being non-conforming.

Production Supervisor:

- Ensure that all personnel operating and cleaning the bottle filling and capping line (BFC-01) are adequately trained on this SOP.
- Oversee the operation of the bottle filling and capping line (BFC-01) and ensure adherence to this SOP.
- Coordinate cleaning and maintenance activities.
- Ensure proper documentation of all activities related to the operation, cleaning, and maintenance of the bottle filling and capping line (BFC-01).
- Report any deviations or malfunctions to the QA Manager and Engineering.

QA Manager:

- Review and approve this SOP.
- Oversee the implementation of this SOP and ensure compliance with GMP guidelines.
- Investigate deviations and implement corrective and preventative actions (CAPA).
- Ensure that all personnel are adequately trained on this SOP.
- Approve cleaning validation protocols and reports.

Head of QA:

- Approve this SOP and any subsequent revisions.
- Ensure overall compliance with GMP requirements related to the bottle filling and capping line (BFC-01).
- Provide final approval of deviation investigations and CAPA plans.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (Nitrile or appropriate material based on product being handled)
- Hairnet/beard cover
- Clean room gown/appropriate apparel
- Mask

Equipment:

- Bottle Filling and Capping Line (BFC-01)

- Vacuum cleaner (HEPA filtered)
- Cleaning solutions (e.g., 70% IPA, Detergent solution - Alconox, WFI)
- Lint-free wipes
- Calibrated weighing scale (BAL-02)
- Torque meter (TOR-01)
- Measuring cylinders (CYL-01, CYL-02)
- Timers (TIM-01)
- Maintenance tools (as per maintenance schedule)

Documentation:

- Batch Production Record (BPR)
- Equipment Logbook (BFC-01-LOG)
- Cleaning Logbook (CLN-LOG-PKG)
- Maintenance Schedule (MNT-SCH-PKG)
- Deviation Report Form (DEV-FRM)
- Training Records (TRN-REC)
- Line Clearance Checklist (LCC-PKG-002)

5.0 PROCEDURE

5.1 Pre-Operation Checks

5.1.1 The Production Supervisor shall verify that the previous batch record is closed and that the line clearance checklist (LCC-PKG-002) has been completed and signed off.

5.1.2 The Production Supervisor shall check the Equipment Logbook (BFC-01-LOG) to ensure that the bottle filling and capping line (BFC-01) is within its calibration and maintenance schedule.

5.1.3 The Production Supervisor shall ensure that the appropriate change parts are installed on the bottle filling and capping line (BFC-01) according to the Batch Production Record (BPR).

5.1.4 The QC Inspector shall inspect the bottle filling and capping line (BFC-01) for cleanliness and compliance with the approved cleaning procedure, verifying against the Cleaning Logbook (CLN-LOG-PKG).

5.1.5 The QC Inspector shall document the cleanliness verification in the Equipment Logbook (BFC-01-LOG). If the line is not clean, the Production Supervisor shall ensure that the line is cleaned according to section 5.3 before proceeding.

5.1.6 The Production Supervisor shall ensure that all necessary materials (bottles, caps, labels, inserts, etc.) are available and have been released by Quality Control.

5.1.7 The Production Supervisor shall verify the material against the Batch Production Record (BPR) to ensure correct materials are used.

5.1.8 The Production Supervisor shall document the material verification in the Batch Production Record (BPR).

5.1.9 The Production Supervisor shall ensure that the appropriate PPE is worn by all personnel involved in the operation.

5.2 Operation of the Bottle Filling and Capping Line (BFC-01)

5.2.1 The Production Supervisor shall ensure that the bottle filling and capping line (BFC-01) is started up according to the manufacturer's instructions and the Standard Operating Procedure for Equipment Startup (SOP-EQP-001).

5.2.2 The Production Supervisor shall verify the initial machine settings (e.g., filling volume, capping torque) according to the Batch Production Record (BPR) and ensure they are correctly set on the bottle filling and capping line (BFC-01).

5.2.3 The Production Supervisor shall conduct a trial run with a small quantity of product to verify the accuracy of the filling volume and capping torque.

5.2.4 The QC Inspector shall perform in-process quality checks during the trial run, including:

- Verification of filling volume using a calibrated weighing scale (BAL-02) and measuring cylinders (CYL-01, CYL-02).
- Verification of capping torque using a calibrated torque meter (TOR-01).
- Visual inspection of the filled and capped bottles for any defects (e.g., leaks, damaged caps).

5.2.5 The QC Inspector shall document the results of the in-process quality checks in the Batch Production Record (BPR).

5.2.6 If the results of the trial run are within acceptable limits, the Production Supervisor shall proceed with the filling and capping operation.

5.2.7 During operation, the Production Supervisor shall continuously monitor the performance of the bottle filling and capping line (BFC-01) and make adjustments as needed to ensure consistent filling volume and capping torque.

5.2.8 The QC Inspector shall perform in-process quality checks at regular intervals (e.g., every 30 minutes) during the operation, following the same procedure as the trial run.

5.2.9 The QC Inspector shall document the results of the in-process quality checks in the Batch Production Record (BPR).

5.2.10 If any deviations are observed during operation, the Production Supervisor shall stop the bottle filling and capping line (BFC-01) and investigate the cause of the deviation.

5.2.11 The Production Supervisor shall document any deviations and corrective actions taken in the Deviation Report Form (DEV-FRM) and Batch Production Record (BPR).

5.2.12 Once the deviation has been resolved, the Production Supervisor and QC Inspector shall approve the resumption of the filling and capping operation.

5.2.13 At the end of the filling and capping operation, the Production Supervisor shall ensure that all filled and capped bottles are properly labeled and packaged.

5.2.14 The Production Supervisor shall reconcile the quantity of filled and capped bottles with the quantity of product used.

5.2.15 The Production Supervisor shall document the reconciliation in the Batch Production Record (BPR).

5.3 Cleaning of the Bottle Filling and Capping Line (BFC-01)

5.3.1 The Production Supervisor shall ensure that the bottle filling and capping line (BFC-01) is cleaned immediately after each batch, or more frequently if required, according to the approved cleaning procedure (SOP-CLN-001).

5.3.2 The Production Supervisor shall ensure that the cleaning procedure is performed by trained personnel.

5.3.3 The Production Supervisor shall ensure that all residual product and packaging materials are removed from the bottle filling and capping line (BFC-01).

5.3.4 The Production Supervisor shall disassemble the bottle filling and capping line (BFC-01) as necessary to facilitate cleaning.

5.3.5 The Production Supervisor shall clean all surfaces of the bottle filling and capping line (BFC-01) with the designated cleaning solutions (e.g., 70% IPA, Detergent solution - Alconox, WFI) and lint-free wipes.

5.3.6 The Production Supervisor shall rinse all surfaces with Water for Injection (WFI) to remove any residual cleaning solutions.

5.3.7 The Production Supervisor shall dry all surfaces with lint-free wipes or allow them to air dry.

5.3.8 The Production Supervisor shall reassemble the bottle filling and capping line (BFC-01) after cleaning.

5.3.9 The QC Inspector shall visually inspect the bottle filling and capping line (BFC-01) for cleanliness after cleaning.

5.3.10 The QC Inspector shall document the cleaning in the Cleaning Logbook (CLN-LOG-PKG).

5.3.11 If required by the cleaning validation protocol, the QC Inspector shall collect swab samples from the bottle filling and capping line (BFC-01) for residue testing.

5.3.12 The QC Inspector shall send the swab samples to the quality control laboratory for analysis.

5.3.13 The QC Inspector shall review the residue testing results and document the results in the Cleaning Logbook (CLN-LOG-PKG).

5.4 Maintenance of the Bottle Filling and Capping Line (BFC-01)

5.4.1 The Engineering Department shall perform preventative maintenance on the bottle filling and capping line (BFC-01) according to the Maintenance Schedule (MNT-SCH-PKG).

5.4.2 The Engineering Department shall document all maintenance activities in the Equipment Logbook (BFC-01-LOG).

5.4.3 The Engineering Department shall calibrate the bottle filling and capping line (BFC-01) according to the calibration schedule.

5.4.4 The Engineering Department shall document all calibration activities in the Equipment Logbook (BFC-01-LOG).

5.4.5 If any repairs are required on the bottle filling and capping line (BFC-01), the Engineering Department shall perform the repairs and document the repairs in the Equipment Logbook (BFC-01-LOG).

5.4.6 The Production Supervisor shall notify the Engineering Department of any malfunctions or maintenance needs.

6.0 POST-ACTIVITY ACTIVITIES

6.1 The Production Supervisor shall ensure that all filled and capped bottles are transferred to the quarantine area for further processing.

6.2 The Production Supervisor shall ensure that all unused materials are returned to the designated storage locations.

6.3 The Production Supervisor shall ensure that the Batch Production Record (BPR) is completed and reviewed.

6.4 The Production Supervisor shall ensure that the Equipment Logbook (BFC-01-LOG) is updated with the date, time, and any relevant observations.

6.5 The Production Supervisor shall ensure that the cleaning of the area surrounding the bottle filling and capping line (BFC-01) is completed.

6.6 The Production Supervisor shall verify that the line clearance checklist (LCC-PKG-002) is completed and signed off.

6.7 The Production Supervisor shall notify the QA Manager of any deviations or issues encountered during the operation.

6.8 The QA Manager shall review the Batch Production Record (BPR), Equipment Logbook (BFC-01-LOG), and any deviation reports to ensure compliance with GMP guidelines.

7.0 SAFETY PRECAUTIONS

7.1 All personnel operating the bottle filling and capping line (BFC-01) must be adequately trained and familiar with this SOP.

7.2 All personnel must wear appropriate PPE (safety glasses, gloves, hairnet/beard cover, clean room gown/appropriate apparel, mask) when operating or cleaning the bottle filling and capping line (BFC-01).

7.3 Ensure that the bottle filling and capping line (BFC-01) is properly grounded to prevent electrical shock.

7.4 Use caution when handling cleaning solutions to avoid skin or eye irritation. Refer to the Material Safety Data Sheets (MSDS) for handling instructions.

7.5 Follow lockout/tagout procedures before performing any maintenance on the bottle filling and capping line (BFC-01).

7.6 Be aware of moving parts and pinch points on the bottle filling and capping line (BFC-01).

7.7 Report any safety hazards or incidents to the Production Supervisor immediately.

7.8 No eating, drinking, or smoking is allowed in the packaging area.

7.9 Use caution when lifting heavy objects.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

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