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Operation, Cleaning, and Maintenance of the Fluid Bed Dryer (FBD)

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

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Department: Production

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1.0 PURPOSE

This procedure outlines the standardized operation, cleaning, and preventive maintenance protocols for the Fluid Bed Dryer (FBD), ensuring consistent and controlled drying processes in pharmaceutical manufacturing at NovaThera Pharmaceuticals, thereby maintaining product quality and adherence to Good Manufacturing Practices (GMP).

2.0 SCOPE

This SOP applies to all personnel involved in the operation, cleaning, and maintenance of the Fluid Bed Dryer (FBD), model FBD-200, located in the Production Department, at NovaThera Pharmaceuticals Pvt. Ltd. This procedure is applicable for all pharmaceutical products dried using the FBD, regardless of batch size or specific formulation, unless otherwise specified in a batch-specific manufacturing record. It covers pre-operation checks, drying process parameters, post-operation cleaning, and routine maintenance activities.

3.0 RESPONSIBILITY

QC Inspector:

- Verifies the cleanliness of the FBD prior to use, according to SOP-QA-010, "Visual Inspection of Cleaned Equipment".
- Collects in-process samples as required and performs moisture content analysis per SOP-QC-008, "Moisture Content Determination".
- Reviews batch records and analytical data related to the drying process.

Production Supervisor:

- Ensures that all personnel operating the FBD are adequately trained on this SOP and equipment operation.
- Oversees the drying process, ensuring adherence to established parameters and documenting any deviations.
- Authorizes and verifies the completion of equipment cleaning and maintenance activities.
- Ensures all operational records are completed accurately and completely.

QA Manager:

- Reviews and approves this SOP and any subsequent revisions.
- Conducts periodic audits to verify compliance with this SOP and relevant GMP regulations.
- Investigates any deviations or non-conformances related to the operation, cleaning, or maintenance of the FBD.

Head of QA:

- Provides final approval for this SOP and any subsequent revisions.
- Ensures that the FBD is qualified and maintained in a validated state.
- Oversees the overall quality system related to the FBD operations.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Dust mask or respirator (NIOSH approved)
- Gloves (nitrile or equivalent)
- Protective gown or coveralls
- Earplugs or earmuffs

Equipment:

- Fluid Bed Dryer (FBD-200)
- Vacuum cleaner (HEPA filtered)
- Cleaning brushes (various sizes)
- Cleaning cloths (lint-free)

- Spray bottles
- Weighing balance (BAL-005, calibrated)
- Moisture analyzer (MAC-003, calibrated)
- Timer
- Sieve SFT-02

Documentation:

- Equipment Logbook (EQ-LOG-FBD-200)
- Cleaning Logbook (CLN-LOG-FBD-200)
- Maintenance Logbook (MNT-LOG-FBD-200)
- Batch Manufacturing Record (BMR)
- Deviation Report Form (QA-FRM-002)
- Change Control Form (QA-FRM-001)
- SOP-QA-010, Visual Inspection of Cleaned Equipment
- SOP-QC-008, Moisture Content Determination

5.0 PROCEDURE

5.1 Pre-Operation Checks

5.1.1 The Production Supervisor shall verify that the FBD-200 is clean and ready for use, based on the cleaning logbook (CLN-LOG-FBD-200) and visual inspection. The QC Inspector shall also perform visual inspection for cleanliness as per SOP-QA-010, "Visual Inspection of Cleaned Equipment". Any discrepancies should be reported to the QA Manager immediately and documented in the Equipment Logbook (EQ-LOG-FBD-200).

5.1.2 The Production Supervisor shall ensure the availability of the approved Batch Manufacturing Record (BMR) for the specific product being processed.

5.1.3 The Production Supervisor shall ensure that all required PPE are readily available and in good condition.

5.1.4 The Production Supervisor shall verify that the FBD-200 has a valid calibration sticker.

5.1.5 The Production Supervisor shall check the filter bags of the FBD-200 for any damage or clogging. Replace if necessary, documenting the replacement in the Maintenance Logbook (MNT-LOG-FBD-200). Use only approved replacement filter bags.

5.1.6 The Production Supervisor shall inspect the air inlet and exhaust ducts for obstructions. Clear any obstructions before starting the operation.

5.1.7 The Production Supervisor shall confirm that the FBD-200 is properly grounded.

5.1.8 The Production Supervisor shall verify that the temperature sensors and airflow meters are functioning correctly by comparing readings with calibrated reference instruments, documenting the comparison in the Equipment Logbook (EQ-LOG-FBD-200).

5.1.9 The Production Supervisor shall set the required drying parameters (inlet air temperature, airflow rate, process time) as specified in the BMR.

5.1.10 The Production Supervisor shall perform a dry run of the FBD-200 for 5 minutes to ensure proper airflow and equipment functionality. Observe for any unusual noises or vibrations. Document the dry run in the Equipment Logbook (EQ-LOG-FBD-200).

5.2 Loading the Material

5.2.1 The Production Supervisor shall ensure that the material to be dried is properly weighed and identified according to the BMR.

5.2.2 The Production Supervisor shall carefully load the material into the FBD-200 bowl, ensuring even distribution. Avoid overfilling the bowl.

5.2.3 The Production Supervisor shall securely close and seal the FBD-200 bowl.

5.2.4 The Production Supervisor shall document the material loading in the BMR.

5.3 Drying Process

5.3.1 The Production Supervisor shall initiate the drying process by pressing the "Start" button on the FBD-200 control panel.

5.3.2 The Production Supervisor shall continuously monitor the drying process, paying close attention to the inlet air temperature, exhaust air temperature, airflow rate, and product temperature.

5.3.3 The Production Supervisor shall record the process parameters at regular intervals (e.g., every 15 minutes) in the BMR.

5.3.4 The QC Inspector shall collect in-process samples at the intervals specified in the BMR for moisture content analysis, using SOP-QC-008, "Moisture Content Determination". Document the sampling in the BMR.

5.3.5 The Production Supervisor shall adjust the drying parameters (e.g., inlet air temperature, airflow rate) as necessary to maintain the desired drying rate and prevent overheating, based on the BMR and consultation with the technical services department. Any adjustments should be documented in the BMR, with justification.

5.3.6 If any deviation from the established drying parameters occurs, the Production Supervisor shall immediately stop the process and report the

deviation to the QA Manager. A Deviation Report Form (QA-FRM-002) shall be completed.

5.3.7 The Production Supervisor shall continue the drying process until the desired moisture content, as specified in the BMR, is achieved. The QC Inspector shall confirm the final moisture content.

5.4 Unloading the Material

5.4.1 Once the desired moisture content is achieved, the Production Supervisor shall stop the drying process by pressing the "Stop" button on the FBD-200 control panel.

5.4.2 The Production Supervisor shall allow the FBD-200 to cool down for 15 minutes before unloading the material.

5.4.3 The Production Supervisor shall carefully unload the dried material from the FBD-200 bowl into pre-weighed and labeled containers.

5.4.4 The Production Supervisor shall weigh the containers and record the net weight of the dried material in the BMR.

5.4.5 The Production Supervisor shall seal the containers and transfer them to the next stage of the manufacturing process.

5.4.6 The Production Supervisor shall reconcile the input and output weights, investigating any significant discrepancies. Document the reconciliation in the BMR.

5.5 Cleaning the FBD-200

5.5.1 The Production Supervisor shall ensure that the FBD-200 is thoroughly cleaned after each use, following the cleaning procedure outlined in SOP-CLN-003, "Cleaning of Pharmaceutical Manufacturing Equipment".

5.5.2 The Production Supervisor shall wear appropriate PPE (safety glasses, dust mask, gloves, and protective gown) during the cleaning process.

5.5.3 The Production Supervisor shall remove any residual material from the FBD-200 bowl using a vacuum cleaner (HEPA filtered).

5.5.4 The Production Supervisor shall wash all parts of the FBD-200 (bowl, filter bags, air inlet and exhaust ducts) with a validated cleaning solution, using cleaning brushes and cloths.

5.5.5 The Production Supervisor shall rinse all parts of the FBD-200 thoroughly with purified water.

5.5.6 The Production Supervisor shall dry all parts of the FBD-200 with lint-free cloths or allow them to air dry.

5.5.7 The Production Supervisor shall visually inspect all parts of the FBD-200 for cleanliness. The QC Inspector shall also perform visual inspection for cleanliness as per SOP-QA-010, "Visual Inspection of Cleaned Equipment".

5.5.8 The Production Supervisor shall document the cleaning process in the Cleaning Logbook (CLN-LOG-FBD-200), including the date, time, cleaning solution used, and the name of the person who performed the cleaning.

5.5.9 The Production Supervisor shall store the cleaned FBD-200 in a designated clean area.

5.6 Preventive Maintenance

5.6.1 The Production Supervisor shall ensure that the FBD-200 is maintained according to the preventive maintenance schedule outlined in SOP-MNT-001, "Preventive Maintenance of Pharmaceutical Manufacturing Equipment".

5.6.2 The Production Supervisor shall perform routine maintenance tasks, such as lubricating moving parts, inspecting electrical connections, and replacing worn parts.

5.6.3 The Production Supervisor shall document all maintenance activities in the Maintenance Logbook (MNT-LOG-FBD-200), including the date, time, maintenance task performed, and the name of the person who performed the maintenance.

5.6.4 The Production Supervisor shall report any major repairs or maintenance issues to the engineering department.

6.0 POST-ACTIVITY ACTIVITIES

6.1 The Production Supervisor shall review the Batch Manufacturing Record (BMR) for completeness and accuracy.

6.2 The QC Inspector shall review the in-process and final moisture content results to ensure they meet the specifications outlined in the BMR.

6.3 The Production Supervisor shall submit the completed BMR, Equipment Logbook (EQ-LOG-FBD-200), Cleaning Logbook (CLN-LOG-FBD-200), and Maintenance Logbook (MNT-LOG-FBD-200) to the QA Department for review and approval.

6.4 The QA Manager shall review all documentation for compliance with GMP regulations and company policies.

6.5 The Head of QA shall provide final approval for the batch record and release the material for further processing.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE (safety glasses, dust mask or respirator, gloves, and protective gown) when operating, cleaning, or maintaining the FBD-200.

7.2 Ensure that the FBD-200 is properly grounded to prevent electrical shock.

7.3 Do not operate the FBD-200 if it is damaged or malfunctioning. Report any equipment issues to the engineering department immediately.

7.4 Use caution when handling hot surfaces. Allow the FBD-200 to cool down before cleaning or performing maintenance.

7.5 Avoid inhaling dust generated during the drying process. Use a dust mask or respirator.

7.6 Use validated cleaning solutions for cleaning the FBD-200.

7.7 Do not use flammable solvents near the FBD-200.

7.8 Ensure adequate ventilation in the work area.

7.9 Follow all lockout/tagout procedures when performing maintenance on the FBD-200.

7.10 In case of an emergency, immediately stop the drying process and evacuate the area. Contact the emergency response team.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
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