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Title:	Operation, Cleaning, and Maintenance of the Blender (e.g., V-Blender)	Version:	1.0
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Operation, Cleaning, and Maintenance of the Blender (e.g., V-Blender)

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Production

Title: Operation, Cleaning, and Maintenance of the V-Blender

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1.0 PURPOSE

This procedure outlines the standardized method for the safe and effective operation, cleaning, and maintenance of the V-Blender (BLN-04) at NovaThera Pharmaceuticals, ensuring consistent product quality and adherence to Good Manufacturing Practices (GMP) in pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all personnel involved in the operation, cleaning, and preventative maintenance of the V-Blender (BLN-04) used in the blending of pharmaceutical materials at NovaThera Pharmaceuticals Pvt. Ltd. It covers all blending operations performed using BLN-04, regardless of the specific product or batch size.

3.0 RESPONSIBILITY

QC Inspector:

- Verifies the cleanliness of the V-Blender (BLN-04) prior to use and after cleaning, as per this SOP.

- Collects samples for blend uniformity testing as required by the relevant batch record.
- Documents all inspections and test results accurately and promptly.
- Reports any deviations or non-conformances to the Production Supervisor and QA Manager.

Production Supervisor:

- Ensures that all personnel operating, cleaning, and maintaining the V-Blender (BLN-04) are adequately trained on this SOP.
- Oversees the operation of the V-Blender (BLN-04) and ensures adherence to this SOP.
- Coordinates scheduled maintenance activities and ensures completion.
- Reviews and approves cleaning records and maintenance logs.
- Investigates and resolves any deviations or non-conformances related to the operation, cleaning, or maintenance of the V-Blender (BLN-04).

QA Manager:

- Reviews and approves this SOP and any revisions thereof.
- Provides guidance and oversight to ensure compliance with GMP requirements.
- Reviews deviation investigations and CAPA (Corrective and Preventive Action) plans related to the V-Blender (BLN-04).
- Conducts periodic audits to verify adherence to this SOP.

Head of QA:

- Provides final approval for this SOP and any revisions thereof.
- Ensures the overall quality system compliance related to the operation, cleaning, and maintenance of the V-Blender (BLN-04).

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Dust mask or respirator (NIOSH-approved)
- Gloves (nitrile or suitable chemical-resistant gloves)
- Dedicated cleanroom gown and head covering
- Safety shoes

Equipment:

- V-Blender (BLN-04)
- Cleaning agents (e.g., isopropyl alcohol, detergent solution - see Approved Cleaning Agents List)
- Cleaning cloths (lint-free, dedicated for V-Blender)
- Spray bottles
- Vacuum cleaner with HEPA filter

- Calibration standards for timer and speed settings (if applicable)
- Torque wrench
- Maintenance tools (wrenches, screwdrivers, lubricants)
- pH meter (calibrated)
- Conductivity meter (calibrated)

Documentation:

- V-Blender (BLN-04) Operation Log (Form PROD-003-01)
- V-Blender (BLN-04) Cleaning Log (Form PROD-003-02)
- V-Blender (BLN-04) Maintenance Log (Form PROD-003-03)
- Batch Record
- Approved Cleaning Agents List
- Equipment Calibration Records

5.0 PROCEDURE

5.1 Pre-Operation Inspection and Preparation

1. Before commencing any blending operation, the Production Supervisor must verify that the V-Blender (BLN-04) Cleaning Log (Form PROD-003-02) indicates that the equipment has been cleaned and is in a suitable state for use.
2. The QC Inspector will perform a visual inspection of the V-Blender (BLN-04) to ensure it is clean, dry, and free from any visible residue from previous batches. The inspection will include the internal surfaces of the blending vessel, the discharge valve, and all associated components. The QC Inspector will document the inspection results in the V-Blender (BLN-04) Cleaning Log (Form PROD-003-02).
3. If any residue is observed, the QC Inspector will reject the equipment and notify the Production Supervisor. The V-Blender (BLN-04) must be re-cleaned according to section 5.5 of this SOP.
4. Ensure all PPE requirements as specified in section 4.0 are followed.
5. Verify that the V-Blender (BLN-04) is positioned correctly and securely on its mounting.
6. Ensure the discharge valve is closed and properly sealed.
7. Check that all safety interlocks and emergency stop buttons are functioning correctly.
8. Review the Batch Record for the product to be blended, noting the required blending time, speed, and any specific instructions.
9. The Production Supervisor will enter the date, time, product name, and batch number into the V-Blender (BLN-04) Operation Log (Form PROD-003-01).

5.2 Loading the Materials

1. Ensure the materials to be blended are properly identified and released by QC.
2. Following the instructions in the Batch Record, carefully weigh and measure each ingredient.
3. Gradually add the materials to the V-Blender (BLN-04) through the designated loading port. Avoid overfilling the blending vessel. Typically, the fill level should not exceed 60-70% of the vessel's total volume.
4. While loading, prevent dust generation by using appropriate techniques and enclosures. Ensure the dust collection system (if available) is operating correctly.
5. After all materials have been loaded, securely close and seal the loading port.

5.3 Operating the V-Blender (BLN-04)

1. Set the blending time and speed according to the Batch Record.
2. Initiate the blending process by pressing the "Start" button.
3. Continuously monitor the V-Blender (BLN-04) during operation for any unusual noises, vibrations, or other signs of malfunction.
4. Record the start time and actual blending parameters in the V-Blender (BLN-04) Operation Log (Form PROD-003-01).
5. If any issues are observed, immediately stop the blending process using the emergency stop button and notify the Production Supervisor. Investigate and resolve the issue before resuming operation.
6. The Production Supervisor will verify that all safety guards are in place before restarting the equipment.
7. At the end of the blending cycle, the V-Blender (BLN-04) will automatically stop. If it does not, immediately press the emergency stop button.
8. Record the stop time in the V-Blender (BLN-04) Operation Log (Form PROD-003-01).

5.4 Unloading the Blended Material

1. After the blending cycle is complete, allow the V-Blender (BLN-04) to come to a complete stop.
2. Place a properly labeled container beneath the discharge valve.
3. Carefully open the discharge valve and allow the blended material to flow into the container. Control the flow rate to prevent spillage and dust generation.
4. Use a suitable scoop or spatula (cleaned and dedicated for this purpose) to ensure all material is removed from the blending vessel.
5. Close the discharge valve tightly after all material has been unloaded.
6. The QC Inspector will collect samples of the blended material from the top, middle, and bottom of the container for blend uniformity testing, as specified in the Batch Record. Document the sample collection in the Batch Record.
7. Label the container with the product name, batch number, and date.
8. Transfer the container to the next stage of the manufacturing process according to the Batch Record instructions.

5.5 Cleaning the V-Blender (BLN-04)

1. After unloading the blended material, immediately clean the V-Blender (BLN-04) to prevent product buildup and cross-contamination.
2. Ensure all PPE requirements as specified in section 4.0 are followed.
3. Dry wipe the interior surfaces of the V-Blender (BLN-04) with lint-free cleaning cloths to remove any residual powder.
4. Prepare a cleaning solution according to the Approved Cleaning Agents List and the manufacturer's instructions.
5. Using a spray bottle, apply the cleaning solution to the interior surfaces of the blending vessel, the discharge valve, and all associated components.
6. Scrub the surfaces thoroughly with clean, lint-free cleaning cloths to remove any remaining residue.
7. Rinse the surfaces with potable water, ensuring all traces of the cleaning solution are removed.
8. After rinsing, wipe the surfaces dry with clean, lint-free cleaning cloths.
9. Perform a final visual inspection of the V-Blender (BLN-04) to ensure it is clean and free from any visible residue.
10. The QC Inspector must perform a visual inspection and document the inspection results in the V-Blender (BLN-04) Cleaning Log (Form PROD-003-02). If required by the cleaning validation program, perform swab sampling for residue testing.
11. If any residue is observed, repeat the cleaning process until the equipment is clean.
12. Allow the V-Blender (BLN-04) to air dry completely before its next use.
13. Record the cleaning date, time, cleaning agent used, and the name of the person performing the cleaning in the V-Blender (BLN-04) Cleaning Log (Form PROD-003-02).
14. Store the cleaned V-Blender (BLN-04) in a designated clean area, protected from dust and contamination.

5.6 Preventative Maintenance

1. Preventative maintenance on the V-Blender (BLN-04) will be performed according to the manufacturer's recommendations and a pre-defined schedule.
2. The Production Supervisor will schedule and coordinate all maintenance activities.
3. Maintenance activities may include:
 - Lubricating moving parts (bearings, gears) with approved lubricants.
 - Inspecting and tightening belts and pulleys.
 - Checking and replacing worn seals and gaskets.
 - Verifying the alignment of the blending vessel and drive mechanism.
 - Calibrating the timer and speed settings (if applicable).

- Inspecting and cleaning the electrical connections.
4. Only trained and qualified personnel are authorized to perform maintenance on the V-Blender (BLN-04).
 5. All maintenance activities, including the date, time, description of work performed, and the name of the person performing the maintenance, must be documented in the V-Blender (BLN-04) Maintenance Log (Form PROD-003-03).
 6. If any repairs are required, they must be documented in detail, including the parts replaced and the reason for the repair.
 7. After completing any maintenance or repair work, the Production Supervisor will verify that the V-Blender (BLN-04) is functioning correctly and is safe to operate.

6.0 POST-OPERATION ACTIVITIES

1. The Production Supervisor will review the V-Blender (BLN-04) Operation Log (Form PROD-003-01) and Cleaning Log (Form PROD-003-02) to ensure all entries are complete and accurate.
2. The QC Inspector will review the cleaning logs and any associated analytical testing results to verify the effectiveness of the cleaning process.
3. All completed logs and records will be filed according to NovaThera Pharmaceuticals' document control procedures.
4. Any deviations or non-conformances identified during the operation, cleaning, or maintenance of the V-Blender (BLN-04) will be investigated and documented according to NovaThera Pharmaceuticals' deviation management SOP.
5. The QA Manager will review all deviation investigations and CAPA plans related to the V-Blender (BLN-04).

7.0 SAFETY PRECAUTIONS

1. Always wear the required PPE as specified in section 4.0 when operating, cleaning, or maintaining the V-Blender (BLN-04).
2. Ensure the V-Blender (BLN-04) is properly grounded to prevent electrical shock.
3. Never operate the V-Blender (BLN-04) with the safety guards removed or disabled.
4. Use caution when handling cleaning agents. Refer to the Safety Data Sheets (SDS) for specific safety information.
5. Avoid breathing dust generated during the blending or unloading process. Use a dust mask or respirator if necessary.
6. Do not exceed the maximum fill volume of the blending vessel.
7. Always disconnect the power supply before performing any maintenance or repair work.
8. Ensure the blending area is well-ventilated.

9. Report any unsafe conditions or equipment malfunctions to the Production Supervisor immediately.
10. Follow all applicable safety regulations and guidelines.
11. In case of an emergency, use the emergency stop button and evacuate the area.

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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