



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Vibratory Sifter (30")

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1. To lay down a procedure for Cleaning and Operation of Vibratory Sifter.

2.0 SCOPE:

2.1. This SOP applies to the Cleaning and Operation of Vibratory Sifter in production area.

3.0 RESPONSIBILITY:

3.1. Technical Associate : Cleaning and Operation

3.2. Officer / Executive : Supervision

3.3. Head Production : SOP Compliance

3.4. IPQA Person : Line Clearance

4.0 DEFINITION (S):

4.1. NA

5.0 PROCEDURE:

5.1. "TYPE A" CLEANING:

This is a cleaning procedure for changeover of product with different batches or ascending potency of products at granulation stage and changeover of product with different batches of same potency at coating stage.

5.1.1. Affix "under cleaning" label to the machine.

5.1.2. Enter the cleaning starting time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.3. Ensure that the main power supply is switched off.

5.1.4. Remove the adhered material on the sifter by using vacuum cleaner or by lint free duster.

5.1.5. Remove the adhered material on the control panel earthing bonding system by using vacuum cleaner or by lint free duster.

5.1.6. Dismantle the lid / hood, feed hopper, sieve, S.S. frame, discharge chute, sleeves and gaskets.

5.1.7. Clean the S.S. feed hopper, S.S. frame, holding ring of the sieve and S.S. wire mesh sieve, earthing clamps & sleeves with lint free cloth.



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- 5.1.8. Clean the outlet chute (two nos. in case of double decker), gasket, feed hopper tighten clamp by using lint free cloth.
- 5.1.9. Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer/ QA Officer.
- 5.1.10. Record the cleaning activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2. "TYPE B" CLEANING:

This is a cleaning procedure for Changeover of product with descending potency, different actives / color / after maintenance of any contact parts or after preventive maintenance at granulation stage and changeover of product with ascending or descending potency, different actives/color/after maintenance of any contact parts at coating stage.

If the same product processed for more than a week then also type B cleaning shall be performed.

- 5.2.1. Follow the procedure from step 5.1.1 to 5.1.7
- 5.2.2. Put all the dismantled parts in a virgin poly bag or dismantled parts cover with virgin poly bag. Affixed with "TO BE CLEANED" label and transfer the poly bag to respective cleaning area.
- 5.2.3. Clean the dismantled parts of the sifter using 15-20 liter of purified water for 30/36 inch and 5 to10 liter of purified water for 12 inch Vibro Sifter with nylon brush to remove the adhered material.
- 5.2.4. Clean the sleeves inner side and outer side through 5 -10 litter of purified water.
- 5.2.5. Clean the cleaned parts with 2% sodium lauryl sulfate (For1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.
- 5.2.6. Clean all the dismantled parts with 50-60 liters of purified water for 30 /36 inch and 20-30 liter for 12 inch Vibro Sifter.
- 5.2.7. Clean the sieve by using purified water with a nylon brush.
- 5.2.8. Apply a jet of purified water so as to ensure the complete removal of the previous product.
- 5.2.9. Dry the sieve and sleeves by using compressed air.
- 5.2.10. Wipe the body of the sifter with wet duster soaked in purified water.
- 5.2.11. Dry all the dismantled parts with a dry lint free duster.
- 5.2.12. Wipe all the dismantled parts of the sifter, sleeves and its body with 70% v/v IPA solution and transfer all the cleaned parts to the respective cubicle in virgin poly bag with "CLEANED" label.
- 5.2.13. Record the cleaning activity in Annexure - II ("Cleaning checklist").



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5.2.14. Assemble the sifter without the sieve. Store the sieve and sleeves by covering with a polythene bag separately and label as "CLEANED" status label with date and signature of the production/QA officer. Transfer the cleaned sleeves for storage in change parts storage area.

5.2.15. Transfer the sieve to the change parts storage area and record the utilization and cleaning details in Annexure – I ("Sieve Utilization and Cleaning Record").

5.2.16. Affix label on sifter as "CLEANED" with date and signature of the Production Officer. As per SOP (Status labeling).

5.2.17. Record the cleaning activity of sifter in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.18. If the sifter and the sieve are idle for 72 hours or more, wipe all the parts of the sifter with 70% v/v IPA solution before use. And should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP (Status labeling).

5.2.19. Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.20. Record the sifter sieve utilization and cleaning as per Annexure – I ("Sieve Utilization and Cleaning Record").

5.3. Frequency

5.3.1. Type "A" cleaning is applicable if changeover of product with different batches or ascending potency of products at granulation stage and changeover of product with different batches of same potency at coating stage.

5.3.2. Type "B" cleaning is applicable if changeover of product with descending potency, different actives / color / after maintenance of any contact parts or after preventive maintenance at granulation stage and changeover of product with ascending or descending potency, different actives/color/after maintenance of any contact parts at coating stage.

If the same product processed for more than a week then also type B cleaning shall be performed.

5.3.3. Cleaning is applicable in case of at the end of working day, dedusting of machine with vacuum cleaner or dry by lint free cloth.

NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the machine "before use", with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).



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5.4. OPERATION:

5.4.1. Machine setting:

5.4.1.1. Ensure that the equipment is cleaned and ready for use.

5.4.1.2. Ensure that the main switch is in 'OFF' position.

5.4.1.3. Checks the integrity of gasket and sleeves before assemble then assemble the sieve holding ring and food grade gaskets on the sifter chamber. Sleeves are to be fitted in between discharge chute of Vibro Sifter and product storage container.

5.4.1.4. In case of double Decker, assemble the sieve holding ring along with sieve against another assemble along with sleeves.

5.4.1.5. Visually or using sieve integrity checker to check the sieve integrity of require sieve as per respective BMR. Place the sieve over the sifter chamber and keep the food grade gasket above it and fix the ring by tightening the clamps (where applicable).

5.4.2. Operation:

5.4.2.1. After line clearance from QA, Put the "EQUIPMENT STATUS" label dully filled and signed on the machine.

5.4.2.2. Record the observations in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

5.4.2.3. While sifting the materials, use elbow size hand gloves.

5.4.2.4. Keep the pre-labeled cleaned IPC below the discharge and replace the "CLEANED" label with "EQUIPMENT STATUS" label.

5.4.2.5. Product dedicated sleeves is fitted in between discharge chute of Vibro Sifter and product storage container.

5.4.2.6. Connect the earthing bonding system (P-S) panel to sifter, (P-B) panel to bin & (B-S) bin sifter.



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5.4.2.7. Fitted the sieve as per given in BMR for sifting and detached the clamps in sieve for neutralized the static charge generate during sifting.





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- 5.4.2.8. Switch "ON" the main supply from electrical panel.
- 5.4.2.9. Feed the material to be sifted manually with the help of SS scoop to the sieve.
(In case of L& P device load the material in to the cleaned IPC and position the IPC in to the L & P device above the sifter).
(In case of sifting dried granules, set the sifter below the outlet of tipper).
- 5.4.2.10. Collect the sifted material from the discharge chute of sifter in IPC. Remove the Oversized granules and mill them using Multimill (In case of dried granules).
- 5.4.2.11. Enter the sifting completion time in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.4.2.12. Switch "OFF" the main supply after completion of operation.
- 5.4.2.13. Affix "TO BE CLEANED" labels duly filled and signed on the machine.

5.4.3. **Precaution:**

- 5.4.3.1. Do not run the machine without any material.
- 5.4.3.2. Ensure that the sifting process shall be done near the dust extraction system.
- 5.4.3.3. Ensure that the Vibro Sifter should be connected before operation with crocodile pin at the one end at Vibro Sifter and other end with the hook at the wall.
- 5.4.3.4. After cleaning and before assemble check the integrity of gasket.

6.0 **ABBREVIATION (S):**

- 6.1. IPA : Iso Propyl Alcohol
- 6.2. Q.A. : Quality Assurance
- 6.3. S.S. : Stainless Steel.
- 6.4. SOP : Standard Operating Procedure
- 6.5. No. : Number
- 6.6. BMR : Batch Manufacturing Record
- 6.7. v/v : Volume/Volume
- 6.8. L & P : Lifting and Positioning
- 6.9. IPC : In process Product Container
- 6.10. SLS : Sodium Lauryl Sulphate.

7.0 **REFERENCE (S):**

- 7.1. SOP: Making entries in equipment usage and cleaning log sheet.



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7.2. SOP: Status Labeling.

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure – I	Sieve Utilization and Cleaning Record		Logbook
Annexure – II	Cleaning checklist		Logbook

9.0 DISTRIBUTION:

9.1. **Master Copy** : Quality Assurance

9.2. **Controlled Copy (S):** Production department (02) / Quality Assurance (01)

9.3. **Reference Copy (S):** Production department (05)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
1.	00	NA	New SOP	NA	NA



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ANNEXURE II

Cleaning checklist

Name of the Equipment		VIBRATORY SIFTER	
Equipment I.D. No.		Previous product	
Batch No.		Date	
S.No.	Activity		Activity Performed
1.	Remove the adhered material on the sifter by using vacuum cleaner or by lint free duster.		
2.	Dismantle the lid / hood, feed hopper, sieve, S.S. frame, discharge chute, sleeves and gaskets.		
3.	Clean the S.S. feed hopper, S.S. frame, holding ring of the sieve and S.S. wire mesh sieve, sleeves with lint free cloth.		
4.	Put all the dismantled parts in a virgin poly bag affixed with "TO BE CLEANED" label and transfer to respective cleaning area.		
5.	Clean the dismantled parts of the sifter using 15-20 liter of purified water for 30/36 inch and 5 to 10 liter of purified water for 12 inch Vibro Sifter with nylon brush to remove the adhered material.		
6.	Clean the sleeves inner side and outer side through 5 -10 liter of purified water.		
7.	Clean the cleaned parts with 2% sodium lauryl sulfate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.		
8.	Clean all the dismantled parts with 50-60 liters of purified water for 30 /36 inch and 20-30 liter for 12 inch Vibro Sifter.		
9.	Clean the sieve by using purified water with a nylon brush.		
10.	Apply a jet of purified water so as to ensure the complete removal of the previous product.		



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S.No.	Activity	Activity Performed
11.	Dry the sieve and sleeves by using compressed air.	
12.	Wipe the body of the sifter with wet duster soaked in purified water.	
13.	Dry all the dismantled parts with a dry lint free duster.	
14.	Check the sleeves integrity, before transfer to change parts storage area.	
15.	Check the gasket integrity, before assemble and after cleaning.	
16.	Wipe all the dismantled parts of the sifter and its body with 70% v/v IPA solution and transfer all the cleaned parts to the respective cubicle in virgin poly bag with "CLEANED" label.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put '√' mark if activity performed and put 'X' if activity not performed.