



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Vibratory Sifter (Make-GANSONS)	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Vibratory Sifter (Make-GANSONS).

2.0 SCOPE:

This SOP applies to the Cleaning and Operation of Vibratory Sifter (Make-GANSONS) in Production Area.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Officer and Executive : Supervision

Head Production : SOP compliance

IPQA Person : Line Clearance

4.0 DEFINITION (S):

NA.

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING: Change over from one batch to next batch of the same product, same potency and of similar product with ascending potency

5.1.1 Affix "TO BE CLEANED" label to the machine.

5.1.2 Enter the cleaning starting time in equipment usage log sheet as per SOP.

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 Dismantle the lid, feed hopper, Sieve, SS frame, discharge chute and the gaskets.

5.1.6 Clean the S.S. feed hopper, SS frame, holding the sieve in place and SS wire mesh sieve with lint free cloth.

5.1.7 Clean the outlet chute, rubber gasket, feed hopper tighten clamp by using lint free cloth.

5.1.8 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer/ QA Officer.

5.1.9 Record the cleaning activity in equipment usage log sheet as per SOP.

5.2 "TYPE B" CLEANING: This is a cleaning procedure for Changeover of product with different actives/ color/ descending potency/ If the same product processed for more than a week or after maintenance of contact parts.

5.2.1 Follow the procedure from step 5.1.1 to 5.1.6

5.2.2 Put all the dismantled parts in a virgin poly bag affixed with "TO BE CLEANED" label and transfer the poly bag to respective cleaning area.



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- 5.2.3 Rinse the dismantled parts of the sifter using 10-15 liters of purified water with nylon brush to remove the adhered material.
- 5.2.4 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.
- 5.2.5 Scrub all the dismantled parts with 50-60 liters of purified water.
- 5.2.6 Clean the sieve by using 20 liters of purified water with a nylon brush.
- 5.2.7 Finally rinse with 30-35 liters purified water so as to ensure the complete removal of the previous product.
- 5.2.8 Dry the sieve by using compressed air.
- 5.2.9 Wipe the body of the sifter with wet duster soaked in purified water.
- 5.2.10 Dry all the dismantled parts with a dry lint free duster.
- 5.2.11 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.
- 5.2.12 Record the cleaning activity in Annexure-II.
- 5.2.13 Assemble the sifter without the sieve. Store the sieve by covering with a polythene bag and label as "CLEANED" status label with date and signature of the production/QA officer.
- 5.2.14 Transfer the sieve to the sieve storage area and record the utilization and cleaning details in Annexure –I.
- 5.2.15 Affix label on sifter as "CLEANED" with date and signature of the Production Officer, as per SOP.
- 5.2.16 Record the cleaning activity of sifter in equipment usage log sheet as per SOP.
- 5.2.17 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.
- 5.2.18 Record the 70 % v/v IPA cleaning time of equipment in equipment usage logbook as per SOP.
- 5.2.19 Record the sifter sieve utilization and cleaning as per Annexure –I

5.3 Frequency:

- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product, same potency and of similar product with ascending potency. If same product is processed for more than seven then follow the procedure of type – B cleaning.
- 5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / color / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type - B done after completion of batch.
- 5.3.3 Cleaning is applicable in case of at the end of working day, de-dusting of machine with vacuum cleaner or dry by lint free cloth.



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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.

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 Assemble the sieve holding ring and food grade gaskets on the sifter chamber.
- 5.4.1.4 Visually check the required sieve integrity 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

5.4.2 Operation:

- 5.4.2.1 After line clearance from QA, Put the “UNDER PROCESS” label dully filled and signed on the machine.
- 5.4.2.2 Record the observations in equipment usage log sheet as per SOP.
- 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 “UNDER PROCESS” label.
- 5.4.2.5 Switch “ON” the main supply from electrical panel.
- 5.4.2.6 Feed the material to be sifted manually with the help of SS scoop to the sieve.
- 5.4.2.7 Collect the sifted material from the discharge chute of sifter in IPC. Enter the sifting completion time in equipment usage log sheet as per SOP.
- 5.4.2.8 Switch “OFF” the main supply after completion of operation. Affix “TO BE CLEANED” label 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

6.0 ABBREVIATION (S):

- IPA : Iso Propyl Alcohol
- Q.A. : Quality Assurance



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SS : Stainless Steel.
SOP : Standard Operating Procedure
No. : Number
v/v : Volume/Volume
L & P : Lifting and Positioning
IPC : In process Product Container
SLS : Sodium Lauryl Sulphate

7.0 REFERENCE (S):

SOP: Making entries in Equipment Usage and Cleaning Log Sheet.
SOP: Status Labeling.

8.0 ANNEXURE (S):

Annexure – I : Sieve Utilization And Cleaning Record (Make-GANSONS).
Annexure – II : Cleaning checklist (Make-GANSONS).

9.0 DISTRIBUTION:

Master Copy : Quality Assurance
Controlled Copy (S) : Production department, Quality Assurance
Reference Copy (S) : Production department



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ANNEXURE II

CLEANING CHECKLIST OF VIBRATORY SIFTER (Make-GANSONS)

Name of the Equipment		VIBRATORY SIFTER	
Equipment ID 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, feed hopper, sieves. Frame and discharge chute and the gaskets.		
3.	Clean the S.S. feed hopper, S.S. frame, holding the sieve in place and S.S. wire mesh sieve with lint free cloth.		
4.	Put all the dismantled parts in a virgin poly bag affixed with "TO BE CLEANED" label and transfer the poly bag to respective cleaning area.		
5.	Rinse the dismantled parts of the sifter using 10-15 liters of purified water with nylon brush to remove the adhered material.		
6.	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.		
7.	Scrub all the dismantled parts with 50-60 liters of purified water.		
8.	Clean the sieve by using 20 liters of purified water with a nylon brush.		
9.	Finally rinse with 30-35 liters purified water so as to ensure the complete removal of the previous product.		
10.	Dry the sieve by using compressed air.		
11.	Wipe the body of the sifter with wet duster soaked in purified water.		
12.	Dry all the dismantled parts with a dry lint free duster.		
13.	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.		

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



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Checked By (Prod.)

Verified By (QA)

1.1 Sign/date

Sign/date