



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Sifter Cum Multi-mill	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of Sifter cum Multi-mill.

2.0 SCOPE:

The procedure is applicable to the Cleaning and Operation of Sifter cum Multi-mill in Production department.

3.0 RESPONSIBILITY:

Technical Associate : Operation
Officer/ Executive Production: Supervision
Head Production : SOP Compliance
IPQA : SOP Compliance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

At the end of shift, change over from one batch to next batch of the same product, same potency and of similar product with ascending potency provided the color is same.

- 5.1.1 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.1.2 Ensure that power supply is turned "OFF".
- 5.1.3 Remove the loosely adhered powder from the equipment with the help of vacuum cleaner/dust extractor followed by wiping with a dry lint free cloth.
- 5.1.4 Collect all the powder and dispose it in IPQA disposal waste bin.
- 5.1.5 Remove the screen from the sifting and milling chamber and clean the screen with vacuum cleaner followed by wiping with a dry lint free cloth.
- 5.1.6 Check and ensure the integrity of the Screen as per SOP.
- 5.1.7 Ensure that the equipment is visually clean.
- 5.1.8 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer as per SOP.
- 5.1.9 Clean the area as per SOP.
- 5.1.10 Record the cleaning observations in the equipment usage log sheet as per SOP.



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5.1.11 Record the cleaning observations of screens in the screen utilization and cleaning record.

5.2 "TYPE B" CLEANING:

During changeover of product with different actives / color / descending potency or after maintenance of contact parts.

5.2.1 Ensure that power supply is turned "OFF".

5.2.2 Remove and destroy "TO BE CLEANED" label and affix "UNDER CLEANING" label.

5.2.3 Remove the loosely adhered powder from the equipment with the help of vacuum cleaner followed by wiping with a dry lint free cloth.

5.2.4 Remove top clamp ring and spacing frame from the equipment.

5.2.5 Remove the screen from the equipment.

5.2.6 Keep all the dismantled parts on a polythene lined stainless steel pellet.

5.2.7 Wash all the dismantled parts, screen and external parts with 15 Ltrs. of purified water followed by wiping with a lint free cloth.

5.2.8 Scrub all the dismantled parts, screen and external parts with nylon scrubber to remove adhered material of previous product.

5.2.9 Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)

5.2.10 Finally rinse all the dismantled parts, screen and external parts with 30-45 Ltrs of purified water followed by wiping with a lint free cloth.

5.2.11 Check and ensure that the washed parts and equipment are visually clean.

5.2.12 Open the valve of the compressed air connection.

5.2.13 Remove adhered water from the surface of the dismantled parts with the help of jet of compressed air followed by wiping with a dry lint free cloth.

5.2.14 Close the valve of the compressed air.

5.2.15 Wipe out the cleaned dismantle parts with 70% v/v IPA.

5.2.16 Check and ensure the integrity of the sieves as per SOP.

5.2.17 Assemble all the parts to the sifter cum multi-mill.

5.2.18 Clean the electrical cables and other non-contact parts with 70% IPA followed by wiping with a clean and dry lint free cloth.

5.2.19 Clean the area as per SOP.

5.2.20 Affix duly filled and signed "CLEANED" label on the equipment.



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5.2.21 Record all the observations in the Equipment usage log sheet as per SOP.

5.2.22 Record all the observations in the Equipment usage log sheet as per SOP.

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 days then follow the procedure of type – B cleaning as per SOP.

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 as per SOP.

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 duly sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP.

5.4 EQUIPMENT OPERATION:

5.4.1 Assembling:

5.4.1.1 Ensure "CLEANED" label duly filled and signed is affixed on the equipment. Ensure cleanliness of equipment and area. Remove the "CLEANED" label and affix it in the respective BMR. Affix "UNDER PROCESS" label duly filled and signed on the equipment and record all the observations in the equipment usage log sheet as per SOP.

5.4.1.3 Take out the screen from the sieves and screen cabinet kept in clean equipment area.

5.4.1.4 Check and ensure the integrity of the screen

5.4.2 Start up and operation:

5.4.2.1 Place the outlet of tipper, containing FBD bowl perpendicular above the sifter cum multi-mill charging hopper.

5.4.2.2 Switch 'ON' the sifter.

5.4.2.3 Release the material by opening the valve controlled by actuator through charging hopper.

5.4.2.4 Switch 'ON' the multi-mill as desired speed 'FAST' or 'SLOW'.

5.4.3 Shutdown and unloading:

5.4.3.1 Switch OFF main power supply.

5.4.3.2 Remove the container of sized material with "QUARANTINE" label duly filled and signed on the equipment.



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5.4.3.3 Remove and destroy "UNDER PROCESS" label. Affix "TO BE CLEANED" label duly filled and signed on the equipment.

5.4.3.4 Record all the observations in equipment usage log sheet as per SOP.

6.0 ABBREVIATION (S):

- Lts. : Liters
- IPA : Iso Propyl Alcohol
- SOP : Standard Operating Procedure
- No. : Number
- v/v : Volume/ Volume
- BMR : Batch Manufacturing Record
- QA : Quality Assurance
- SLS : Sodium Lauryl Sulphate

7.0 RERERENCE (S):

- SOP: Making entries in equipment usage and cleaning log sheet.
- SOP: Cleaning Of Production Area.
- SOP: Status Labeling

8.0 ANNEXURE (S):

- Annexure I: Cleaning Checklist of Sifter cum multimill.

9.0 DISTRIBUTION:

- Master Copy** : Quality Assurance
- Controlled Copy (s):** Production department, Quality Assurance
- Reference Copy (s) :** Production department



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ANNEXURE I

CLEANING CHECKLIST OF SIFTER CUM MULTIMILL

Name of the Equipment		Sifter cum Multi-mill	
Equipment ID No.		Previous product	
Batch No.		Date	
S.No.	Activity	Activity performed	
1.	Ensure that the main power supply is switched OFF		
2.	Remove the loosely adhered powder from the equipment with the help of vacuum cleaner followed by wiping with a dry lint free cloth.		
3.	Remove top clamp ring and spacing frame from the equipment.		
4.	Remove the screen from the equipment.		
5.	Keep all the dismantled parts on a polythene lined stainless steel pellet.		
6.	Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water)		
7.	Wash all the dismantled parts, screen and external parts with 15 Ltrs. of purified water followed by wiping with a lint free cloth.		
8.	Scrub all the dismantled parts, screen and external parts with nylon scrubber to remove adhered material of previous product.		
9.	Finally rinse all the dismantled parts, screen and external parts with 30-45 Ltrs. of purified water followed by wiping with a lint free cloth.		
10.	Check and ensure that the washed parts and equipment are visually clean.		
11.	Open the valve of the compressed air connection.		
12.	Remove adhered water from the surface of the dismantled parts with the help of jet of compressed air followed by wiping with a dry lint free cloth.		
13.	Close the valve of the compressed air.		
14.	Wipe out the cleaned dismantle parts with 70% v/v IPA.		

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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