



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Vibro Sifter 30” (Bectochem)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE :

To lay down a procedure for cleaning of Vibro sifter 30” (Bectochem)

2.0 SCOPE :

This SOP is applicable to the cleaning of Vibro sifter 30” (Bectochem) in granulation area.

3.0 RESPONSIBILITY:

Production: Technical Associate/Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 CLEANING : TYPE A

Change over from one batch to next batch of the same product, same potency and of similar product with ascending potency.

4.1.1 Remove “ TO BE CLEANED “ label and affix “ UNDER CLEANING “ label to the machine with date and signature of production officer.

4.1.2 Enter the cleaning starting time in equipment sequential log book as per SOP

4.1.3 Ensure that the main power supply is switched OFF.

4.1.4 Remove the adhered material on the sifter by using vacuum cleaner.

4.1.5 Dismantle the lid, feed hopper, sieve, SS frame, discharge chute, holding clamp and gaskets.

4.1.6 Clean the lid, feed hopper, sieve, SS frame, discharge chute, holding clamp and gaskets with lint free cloth.

4.1.7 Replace the ‘UNDER CLEANING’ status label with “CLEANED” status label with date and signature of the Production Officer.

4.1.8 Record the cleaning activity in equipment sequential log book as per SOP.



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4.2 TYPE B:

This is a cleaning procedure for Change over of product with different actives / color / descending potency or after maintenance of contact parts.

4.2.1 Follow the procedure from step 4.1.1 to 4.1.5.

4.2.2 Transfer the above all parts in respective cleaning area.

4.2.3 Clean the dismantled parts of the sifter using approx. 60.0 to 80.0 kg purified water. Scrub all dismantled parts with nylon scrubber.

4.2.4 Wash all parts with approx. 30.0 to 50.0 kg purified water. Rinse all parts with approx. 30.0 to 40.0 kg purified water.

4.2.5 Clean the sieve by using approx. 50.0 to 60.0 kg purified water. Scrub it with nylon scrubber.

4.2.6 Rinse the sieve by applying approx. 20.0 to 30.0 kg of purified water so as to ensure the complete removal of the previous product.

4.2.7 Dry the sieve by using compressed air followed by clean dry lint free cloth.

4.2.8 Wipe the body of the sifter with wet duster soaked in purified water.

4.2.9 Dry all the dismantled parts by compressed air followed by dry lint free duster.

4.2.10 Wipe all dismantled parts of the sifter and its body with 70% v/v IPA solution.

4.2.11 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 officer.

4.2.12 Transfer the sieve to the sieve storage area.

4.2.13 Affix label on sifter as “CLEANED” with date and signature of the Production Officer.

4.2.14 Record the cleaning activity in equipment sequential log as per SOP.

5.0 ANNEXURE (S) :

Nil



PHARMA DEVILS

PRODUCTION DEPARTMENT

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6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

SOP: Procedure for area line clearance.

7.0 ABBREVIATION (S) / DEFINITION (S):

SOP: Standard Operating Procedure

BMR : Batch Manufacturing Record

SS : Stainless Steel

IPA : Iso Propyl Alcohol

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---