



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning of Multi mill	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE :

To lay down a procedure for cleaning of Multimill (Bectochem)

2.0 SCOPE :

This SOP is applicable to the cleaning of Multimill (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 Multimill by using vacuum cleaner.

4.1.5 Dismantle the discharge hopper, base plate, screen, beater assembly and the gaskets.

4.1.6 Clean the feeding port, beater assembly, discharge hopper, base plate, screen 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.

4.2 TYPE B:

This is a cleaning procedure for Change over of product with different actives /



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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 Multi mill using approx. 60.0 to 80.0 kg purified water. Scrub all dismantled parts with nylon scrubber.
- 4.2.4 Wash all the parts using approx. 30.0 to 50.0 kg purified water.
- 4.2.5 Rinse all parts with approx. 20.0 to 30.0 kg purified water.
- 4.2.6 Clean the screen by using approx. 20.0 to 30.0 kg purified water and scrub it with nylon scrubber.
- 4.2.7 Wash the screen using approx. 10.0 to 20.0 kg purified water.
- 4.2.8 Rinse the screen by applying approx. 10.0 to 20.0 kg purified water so as to ensure the complete removal of the previous product.
- 4.2.9 Dry the screen by using compressed air followed by clean dry lint free cloth.
- 4.2.10 Wipe the body of the Multimill with wet duster soaked in purified water.
- 4.2.11 Dry the dismantled parts with compressed air followed by dry lint free duster.
- 4.2.12 Wipe all dismantled parts of the Multimill and its body with 70% v/v IPA solution.
- 4.2.13 Assemble the Multimill without screen. Store the screen by covering with a polythene bag and label as 'CLEANED' status label with date and signature of the production officer.
- 4.2.14 Transfer the screen to the screen storage area.
- 4.2.15 Affix label on Multimill as "CLEANED" with date and signature of the Production Officer.
- 4.2.16 Record the cleaning time in equipment sequential log book as per SOP.

5.0 ANNEXURE (S) :

Nil

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard



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Operating Procedure (SOP).

SOP: Procedure for area line clearance.

SOP: Status Labeling in Production Dept.

SOP: Procedure for Inventory, cleaning and storage of sieves and screens.

7.0 ABBREVIATION (S) / DEFINITION (S):

SOP: Standard Operating Procedure

BMR : Batch Manufacturing Record

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	---