



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning of Co-mill 10 HP

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE :

To lay down a procedure for cleaning of Co-mill 10 HP (Bectochem).

2.0 SCOPE :

This SOP is applicable to the cleaning of Co-mill 10 HP (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 start 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 Co-Mill by clean dry lint free cloth.

4.1.5 Dismantle the hose pipe, discharge hopper with suction chute, screen and the gaskets.

4.1.6 Clean the feeding port, beater assembly, discharge hopper with suction chute, screen and gaskets with clean dry 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 completion time 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 / color /



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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 Cover the electrical panel and motor with polyethylene bags.
- 4.2.3 Transfer the above all parts in respective cleaning area.
- 4.2.4 Clean the dismantled parts of the Co-Mill using approx. 30.0 to 35.0 kg of purified water. Scrub all dismantled parts with nylon scrubber.
- 4.2.5 Wash all parts with approx. 25.0 to 35.0 kg of purified water. Rinse all parts with approx. 15.0 to 20.0 kg of purified water.
- 4.2.6 Clean the screen by using approx. 15.0 to 20.0 kg of purified water and scrub it with nylon scrubber.
- 4.2.7 Rinse the screen by using approx. 15.0 to 20.0 kg of purified water so as to ensure the complete removal of the previous product.
- 4.2.8 Dry the screen by using compressed air followed by clean dry lint free cloth.
- 4.2.9 Remove the polyethylene bags and wipe the body, motor cover of Co-Mill with wet duster soaked in purified water.
- 4.2.10 Dry the dismantled parts with compressed air followed by clean dry lint free cloth.
- 4.2.11 Wipe all dismantled parts of the Co-mill with clean lint free cloth soaked in 70 % v/v IPA solution.
- 4.2.12 Assemble the Co-Mill 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.
- 4.2.13 Transfer the screen to the screen storage area.
- 4.2.14 Affix label on co-mill as "CLEANED" with date and signature of the Production Officer.
- 4.2.15 Record the cleaning completion 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



PHARMA DEVILS

PRODUCTION DEPARTMENT

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Operating Procedure (SOP).

SOP: Procedure for area line clearance.

7.0 ABBREVIATION (S) / DEFINITION (S):

SOP: Standard Operating Procedure

BMR : Batch Manufacturing Record

IPA : Isopropyl Alcohol

v/v : volume/volume

kg : Kilogram

REVISION CARD

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