



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Colloid Mill

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE :

To lay down a procedure for operation & cleaning of Colloid Mill.

2.0 SCOPE :

This procedure is applicable to the operation & cleaning of Colloid Mill in coating area.

3.0 RESPONSIBILITY:

Production: Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Operation:

4.1.1 After the line clearance from Q.A., put the "UNDER PROCESS" label on the machine.

4.1.2 Enter the start time of batch in equipment sequential log as per SOP.

4.1.3 Put the switch "ON" by turning the plug in clockwise direction.

4.1.4 Press the "Start" switch provided on Colloid mill.

4.1.5 Ensure that the direction of rotation of the rotor is always clockwise

4.1.6 Before starting the machine, adjust the grinding slit by unscrewing both the handles to adjust the ring. Turn the handles in clockwise or anti-clockwise to get the desired grinding mass. After the adjustment tighten the ring by screwing the handles.

Note: Clockwise for finer grinding mass and anticlockwise for coarse grinding mass.

4.1.7 Pour the material into the hopper slowly. Check the circulation of the material.

4.1.8 Mill the material as per time mention in BMR and record it.

4.1.9 Enter the completion time of the milling of solution in equipment sequential log as per SOP.

4.1.10 Press the "Stop" switch provided on Colloid mill.

4.1.11 Put the switch " OFF " by turning the plug in anticlockwise direction



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4.1.12 Replace the 'UNDER PROCESS' Label with "TO BE CLEANED" label on the machine.

4.2 Cleaning:

4.2.1 TYPE A:

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

4.2.1.1 Remove " TO BE CLEANED " label and affix " UNDER CLEANING " label to the machine.

4.2.1.2 Enter the cleaning start time in equipment sequential log as per SOP.

4.2.1.3 Connect the power supply and switch on the colloid mill. Allow flowing of purified water to pass through the assembly of colloid mill. Pass the purified water till the product is washed out from colloid mill.

4.2.1.4 Rinse the mill and parts with purified water.

4.2.1.5 Disconnect the power supply and clean the utility cables by using dry lint free duster.

4.2.1.6 Cover the colloid mill with lid after cleaning if not used for operation.

4.2.1.7 Remove the "UNDER CLEANING" status label and affix the "CLEANED" status label.

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

4.2.2 TYPE B:

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

4.2.2.1 Follow the procedure from step 4.2.1.1 to 4.2.1.2

4.2.2.2 Disconnect the power supply and clean the utility cables by using a dry lint free cloth.

4.2.2.3 Dismantle the colloid mill except of the motor and shaft.

4.2.2.4 Clean the S.S hopper, 'J' shaped S.S pipe, Gasket and valve from the inside and the outside with purified water by using nylon scrubber.

4.2.2.5 Rinse the parts with 25-30 Kg of purified water to remove the traces of the previous product.

4.2.2.6 Rinse the hopper, 'J' shaped S.S pipe, gaskets and valve thoroughly with 15-20 Kg purified water.

4.2.2.7 Dry the parts with compressed air and wipe the parts of the machine with a lint free dry



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duster.

- 4.2.2.8 Wipe the outside of the colloid mill with a wet lint free duster and then dry with a lint free duster.
- 4.2.2.9 Sanitize the hopper, the 'J' shaped S.S pipe, gaskets, the outside of the colloid mill and all contact parts with 70% v/v IPA solution. Reassemble the machine parts.
- 4.2.2.10 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the production officer.
- 4.2.2.11 Replace the previous 'CLEANED' status label with current date 'CLEANED' status label with date and signature of the production officer.
- 4.2.2.12 Record the cleaning activity in equipment sequential log as per SOP.

5.0 ANNEXURE (S) :

Nil

6.0 REFERENCE (S):

SOP: Procedure for line clearance.

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

7.0 ABBREVIATION (S) /DEFINITION (S) :

QA : Quality Assurance

SOP : Standard Operating Procedure

V/V : Volume / Volume

IPA : Isopropyl Alcohol

REVISION CARD

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