



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Colloidal Mill	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Colloidal Mill.

2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Colloidal Mill.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation Colloidal Mill.

3.2 Production Officer / Executive: Checking cleaning Operation Colloidal Mill.

3.3 Head Production : SOP Compliance of Cleaning and Operation Colloidal Mill.

3.4 IPQA Person : Verification and Line Clearance

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING: This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.

5.1.1 Switch off the electric supply and disconnect the plug of colloid mill.

5.1.2 Pull the colloid mill to the wash area.

5.1.3 Close the outlet valve of Colloid Mill. Run the colloid mill with 30 liters of purified water for 05 minutes by recirculating the water.

5.1.4 Open the outlet valve and remove the washing water in a container and drain it.

5.1.5 Switch off the electric supply and rub the reachable area with clean lint free cloth.

5.1.6 Switch ON the colloid mill and rinse the colloid mill with 10 liters of purified water and drain the water from outlet.

5.1.7 Switch OFF the colloid mill.

5.1.8 Wipe the out side of Colloid Mill with a clean lint free cloth.

5.1.9 Close the outlet valve and put the SS Cover on the hopper.

5.1.10 Put "CLEANED" status on the equipment as per reference SOP ("Status labeling").



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Issue Date:

Page No.:

5.1.11 Record the details of machine cleaning in equipment usage log sheet as per reference SOP (“Making entries in equipment usage and cleaning log sheet”).

5.2 “TYPE B” CLEANING: This is a cleaning procedure for Changeover of product with different actives / colour / ascending potency / descending potency or after maintenance of contact parts.

5.2.1 Switch OFF the electric supply and disconnect the plug.

5.2.2 Pull the colloid mill to the wash area.

5.2.3 Close the outlet valve of Colloid Mill. Run the colloid mill with 30 liters of purified water for 05 minutes by recirculating the purified water. Open the outlet valve and remove the washing water in a container and drain it.

5.2.4 Dismantle the parts of Colloid Mill – Hopper, S.S Cover, re-circulation pipe, rotor, stator and cock body assembly.

5.2.5 Clean the hopper, SS. Cover, re-circulation pipe, rotor, stator and cock body assembly with 20 liters of purified water and rubbing with clean lint free cloth and nylon brush.

5.2.6 Air dry all the dismantle parts and wipe out all the clean dismantle parts with 70% IPA.

5.2.7 Reassemble the colloidal mill.

5.2.8 Wipe the out side of Colloid Mill with a clean lint free cloth.

5.2.9 Inform QA personnel to collect swab / rinse water sample if required.

5.2.10 Put “CLEANED” status on the equipment as per reference SOP (“Status labeling”).

5.2.11 Record the details of machine cleaning in equipment usage log sheet as per reference SOP (“Making entries in equipment usage and cleaning log sheet”).

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 (“Cleaning verification”).

5.3.2 Type ‘B’ cleaning is applicable in case of change over of product with different actives/colour/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 (“Cleaning verification”).

5.3.3 Cleaning is applicable in case of at the end of working day, de-dusting of machine with vacuum cleaner or dry by lint free cloth.



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Issue Date:	Page No.:

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 dully sign the “CLEANED” label again. Record the activity in equipment usage log sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.4 Operation:

- 5.4.1 Ensure that Colloid mill is cleaned. Take line clearance from QA, and then put the ‘EQUIPMENT STATUS’ label on machine.
- 5.4.2 Set the milling gap as per the BMR requirement and if re-circulation is required adjust the 3-way cock accordingly.
- 5.4.3 Before starting the machine, adjust the grinding slit by securing both the handles out of the adjusting ring until the ring freely turns. Turn the handles in clockwise direction to get a finer grinding slit, or anti-clockwise to increase the opening. After the adjustment, block the ring by screwing the handles.
- 5.4.4 Connect the discharge spout of the mill to inlet of tank with silicon tubing if required.
- 5.4.5 Check the mill for correct direction of rotation i.e. clock wise.
- 5.4.6 Close the discharge spout and start the colloid mill by green push button ‘ON’.
- 5.4.7 Pour the material into the hopper slowly. Check the revolution of the material.
- 5.4.8 Start the feed to mill hopper and open the discharge spout from cock handle.
- 5.4.9 On completion of the process and when the hopper is empty stop the colloid mill from Red push button.
- 5.4.10 After completion of batch Affix the ‘TO BE CLEANED’ label.
- 5.4.11 Enter operation details in Equipment Usages Log Sheet as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.5 Precaution:

- 5.5.1 Check that mill runs first and then product is fed.
- 5.5.2 Check that mill is stopped after product drained off.
- 5.5.3 Never leave the machine with product overnight.
- 5.5.4 Never keep drain open while pouring product in hopper.
- 5.5.5 Never put oil or grease inside the main housing

6.0 ABBREVIATION (S):

- 6.1 QA : Quality Assurance
- 6.2 SOP : Standard operating procedure



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6.3 No. : Number

6.4 NA : Not applicable

6.5 S.S : Stainless steel

7.0 REFERENCE (S):

7.1 SOP: Status labeling.

7.2 SOP: Making entries in equipment usage and cleaning log sheet.

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of execution
Annexure - I	Cleaning checklist colloidal mill		Log book

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled Copy (S)** : Production department (01), Quality Assurance

9.3 **Reference Copy (S)** : Production department (02)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) For Revision	Details of Revision	Effective Date
01	00		New SOP	NA	



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ANNEXURE I

Cleaning Checklist of Colloid Mill

Name of the Equipment	COLLOID 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.	Pull the colloid mill to wash area for cleaning.	
3.	Close the outlet valve of Colloid Mill. Run the colloid mill with 30 liters of purified water for 05 minutes by recirculating the purified water. Open the outlet valve and remove the washing water in a container and drain it.	
4.	Dismantle the parts of Colloid Mill – Hopper, S.S Cover, re-circulation pipe, rotor, stator and cock body assembly.	
5.	Clean the hopper, SS. Cover, re-circulation pipe, rotor, stator and cock body assembly with 20 liters of purified water and rubbing with clean lint free cloth and nylon brush.	
6.	Air dry all the dismantle parts and wipe out all the clean dismantle parts with 70% IPA.	
7.	Reassemble the colloidal mill.	
8.	Wipe the outside of Colloid Mill with a clean lint free cloth.	
9.	Put “CLEANED” status on the equipment as per reference SOP No.QA/044	

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date