PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Operation and Cleaning of Colloidal Mill	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for operation and cleaning of colloidal mill used in production department.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

%	Percent
BPCR	Batch Production and Control Record
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless Steel
v/v	Volume by Volume

6.0 PROCEDURE:

6.1 OPERATION OF COLLOIDAL MILL:

6.1.1 Check & ensure that Colloidal Mill and its surrounding area is cleaned properly.

6.1.2 Take line clearance from QA as per" Line clearance "SOP"'.

6.1.3 Start chilled water circulation in the jacket in the jacket of colloid mill. (Where applicable)

6.1.4 Switch "ON" the mains and of the colloidal mill.

6.1.5 Set the colloidal mill with zero apertures before colliding the material.

6.1.6 Load the material to the hopper of colloidal mill and close the outlet valve.

6.1.7 Re-circulate the material by opening the re-circulate valve at least 5 minute or as specified in BPCR.

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6.1.8 Open the outlet valve and close the re-circulate valve of colloidal mill and collect the suspension in SS container.

6.1.9 Switch "OFF" the colloidal mill and Switch "OFF" the mains.

6.1.10 Close the chilled water re-circulate valve if it is applied.

6.1.11 Mark the status label "To be Cleaned" to the colloidal mill after completion of work.

6.1.12 Enter the operation details in Machine Utilization record and BPCR.

6.2 CLEANING OF COLLOIDAL MILL:

6.2.1 For Product Changeover (Type B Cleaning) :

6.2.1.1 Check and ensure that there is no previous material residue in the hopper of colloidal mill.

6.2.1.2 Switch "ON" the mains and colloidal mill.

6.2.1.3 Clean the colloidal mill with 2.0% v/v solution of Extran MA-02.

6.2.1.4 Close the outlet valve of colloidal mill then load the Extran MA-02 solution in hopper of colloidal mill.

6.2.1.5 Re-circulate the Extran MA-02 by opening the re-circulating valve of colloidal mill.

6.2.1.6 Close the re-circulating valve and open the outlet valve of colloidal mill and collect the solution in SS container and drain it.

6.2.1.7 Wash the colloidal mill through hot Potable / purified water by loading into the hopper and close the outlet valve & open the re-circulating valve of colloidal mill and recalculate the loaded potable/ purified water.

6.2.1.8 Open the outlet valve and collect the water in SS container and drain it in washing area.

6.2.1.9 Repeat the above procedure.

6.2.1.10 Finally wash with sufficient quantity of Potable/ purified water.

6.2.1.11 Check & ensure that the previous material residue is completely removed.

6.2.1.12 Rinse with sufficient quantity of purified water

6.2.1.13 Clean the outer surface with wet lint free cloth followed by dry lint free cloth.

6.2.1.14 Affix a "Cleaned" label on the Colloidal Mill.

6.2.1.15 Make the entry in "Machine Utilization Record".

6.2.2 For Batch Changeover (Type A Cleaning) :

6.2.2.1 Check and ensure that there is no previous material residue in the hopper of colloidal mill.

6.2.2.2 Switch "ON" the mains and colloidal mill.

6.2.2.3 Clean with sufficient quantity of Potable water followed by purified water.

6.2.2.4 Clean the outer surface with wet lint free cloth followed by dry lint free cloth.

6.2.2.5 Make the entry in "Machine Utilization Record".

6.2.3 Frequency of batch to batch cleaning (Type A Cleaning)

(a) Changeover from one batch to next batch of same product with same potency.

(b) Changeover from one batch to next batch of the same product with higher potency.

6.2.4 Frequency of product to product cleaning (Type B Cleaning) :

(a) Product to product changeover.

(b) If cleaned equipment is kept idle more than 72 hours.

(c) If Dirty equipment is kept idle more than 24 hours.

(d) After 5 batch of the same product.

(e) After any maintenance of product contact parts.

(f) Changeover of one batch to next batch of the same product with descending potency.

(g) In case of color change (Any strength)

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Operating Manual

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By