PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production (Softgel)	**SOP No.:**
Title: Cleaning of Utensils and Accessories	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for Operation and Cleaning of Colloid Mill.

2.0 SCOPE:

This procedure is applicable for the Operation and Cleaning of Colloid Mill in medicament and gelatin manufacturing department.

3.0 RESPONSIBILITY:

Technician/ Officer/ Executive/ Manager-Production.

Head of Department: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Operation

4.1.1 Ensure cleanliness of the equipment and area.

4.1.2 Ensure that environmental conditions are within the limit as per given in the BMR.

4.1.3 Ensure that all the doors are closed and no chance of cross- contamination.

4.1.4 Ensure that the direction of rotation of the Colloid Mill is clockwise.

4.1.5 Adjust the grinding slit by securing both the handles until the ring freely turns.

4.1.6 Update the “AREA STATUS BOARD” with duly filled and signature of production officer.

4.1.7 Take the line clearance from QA personnel as per SOP.

4.1.8 Remove “CLEANED” label from the Colloid Mill and affix the “STATUS LABEL” on the equipment and machine with duly filled and signature of the production officer.

4.1.9 Enter the operation start time in equipment usage log book as per SOP.

4.1.10 Open the chilled water circulation of the Colloid Mill before starting the milling process.

4.1.11 Open the return valve of the colloid mill and close the discharge valve and pour the

material into the hopper slowly while switch "OFF" the machine.

4.1.12 Switch "ON" the main supply of the Colloid Mill and re-circulate the material as per given in the BMR.

4.1.13 After completion of milling process switch "OFF" the main power supply.

4.1.14 Enter the Colloid Mill operation complete time in the equipment usage log book as per SOP.

4.1.15 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the equipment with duly filled and signature of production officer.

4.2 CLEANING PROCEDURE

4.2.1 Cleaning procedure Type A

Changeover from one batch to next batch of the same colour of product and same potency and of similar product with ascending potency.

4.2.1.1 Remove "TO BE CLEANED" label from the equipment and machine and update the "AREA STATUS BOARD" with duly filled and signature of production officer.

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

4.2.1.3 Transfer the colloid mill in washing area and close the out let valve.

4.2.1.4 Connect the power supply and fill the hopper with purified water up to 70 % of the hopper volume.

4.2.1.5 Switch "ON" the main supply of the Colloid Mill and re-circulate for 5 minutes.

4.2.1.6 This process is to be repeat till completely removing of colour.

4.2.1.7 Finally clean the all part with purified water.

4.2.1.8 Dry the Colloid Mill with the help of compressed air. clean the outer surface and hopper with dry lint free cloth followed by 70% v/v IPA solution.

4.2.1.9 Cover the outlet and re-circulating pipe with plain aluminum foil.

4.2.1.10 Affix "CLEANED" label on the equipment with duly filled and signature of production officer.

4.2.1.11 Record the cleaning complete time in equipment usage log book as per SOP.

4.2.1.12 For medicament cleaning use medicament vehicle for cleaning.

4.2.1.13 Fill the hopper with medicament vehicle and re-circulate for 5 minutes then discard the filled vehicle.

4.2.1.14 Clean the inner and outer surface with dry lint free cloth followed by 70 % v/v IPA solution.

4.2.1.15 Cover the outlet and re-circulating pipe with plain aluminum foil.

4.2.1.16 Affix "CLEANED" label on the equipment and machine and update the "AREA STATUS BOARD" with duly filled and signature of production officer.

4.2.1.17 Record the cleaning complete time in the equipment usage log book as per the SOP.

4.2.2 Cleaning procedure Type B

This is a cleaning procedure for product changeover of different product, active/ colour/ descending potency or after maintenance of contact parts.

4.2.2.1 Remove "TO BE CLEANED" label from the equipment, machine and update the "AREA STATUS BOARD" with duly filled and signature of production officer.

4.2.2.2 Enter the cleaning start time in equipment usage log book as per SOP.

4.2.2.3 Transfer the Colloid Mill in washing area.

4.2.2.4 Close the discharge valve and open re-circulating valve.

4.2.2.5 Connect the power supply and fill the hopper with purified water up to 70 % of the hopper volume.

4.2.2.6 Re-circulate for 5 minutes this process is to be re-peat till completely removing of colour and discard the colored water in washing area.

4.2.2.7 Then fill the hopper of the Colloid Mill with 1.0 % v/v teepol solution.

4.2.2.8 Circulate the teepol solution in Colloid Mill for 5 minutes and discharge the washing solution to the washing area.

4.2.2.9 Again fill the hopper with purified water and re-circulate for proper cleaning of traces of the teepol solution.

4.2.2.10 Dismantle the discharge and re-circulating pipe. Then it clean with hot water with 1.0 % teepol solution.

4.2.2.11 Ensure that there is no traces of medicament or colour inside the hopper and grinder.

4.2.2.12 Dry the colloid mill and all parts with compressed air.

4.2.2.13 Clean the colloid mill with dry lint free cloth followed by 70% v/v IPA solution.

4.2.2.14 Affix "CLEANED" label on the equipment with duly filled and signature of production officer.

4.2.2.15 Record the cleaning complete time in equipment usage log book as per SOP.

4.3 Precautions

4.3.1 Never put oil or grease inside the main housing.

4.3.2 Never leave the machine with material overnight or for a long time.

4.3.3 Never run the colloid mill without chilled water supply.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP: Procedure of filling of equipment log book.

SOP: Procedure for Area Line clearance.

SOP: Preparation, approval, distribution control, revision and destruction of standard operating procedure.

7.0 ABBREVIATION (S) / DEFINITION (S):

BMR : Batch Manufacturing Record

QA : Quality Assurance

SOP : Standard Operating Procedure

IPA : Iso Propyl Alcohol

v/v : Volume/ Volume

PRD : Production Department

REVISION CARD

S.No.	REVISION	REVISION	DETAILS OF	REASON (S)	REFERENCE

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