



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (Soft Gel)	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Medicament Mixing Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE :

To lay down the procedure for Operation and Cleaning of Medicament Mixing Unit.

### 2.0 SCOPE :

This procedure is applicable for the Operation and Cleaning of Medicament Mixing Unit in medicament preparation area.

### 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 "CLEANED" label affix on the Medicament Mixing Unit.

4.1.4 Ensure that BMR is available and all the entry is properly completed till this stage.

4.1.5 Ensure that all the containers are properly cleaned, labeled and kept properly on a pallet at proper place.

4.1.6 Ensure that Chilled water, Vacuum, Nitrogen supply and other utilities are required working properly as per specifications mentioned in BMR.

4.1.7 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.

4.1.8 Take line clearance from QA personnel.

4.1.9 Remove "CLEANED" label from the Medicament Mixing Unit and affix the "STATUS LABEL" with duly filled and signature of production officer.

4.1.10 Cross check the weight of dispensed medicament raw materials by weighing according to the materials issuance sheet BMR.



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production (Soft Gel)	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Medicament Mixing Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 4.1.11 Switch "ON" the Sodium lamp and put "OFF" the fluorescent light in case of light sensitive products.
- 4.1.12 Switch "ON" the main electric supply of the Medicament Mixing Unit from the electric panel.
- 4.1.13 Enter the operation start time of the Medicament Mixing Unit in equipment usage log book as per SOP.
- 4.1.14 Push "UP" button to lift up the Medicament Mixing Unit lid.
- 4.1.15 Transfer the material into Medicament Mixing Unit step wise as per the procedure described in BMR.
- 4.1.16 After transfer of all raw materials into the Medicament Mixing Unit Push "DOWN" button to Down the Medicament Mixing Unit lid.
- 4.1.17 Switch "ON" the stirrer of the Medicament Mixing Unit till proper mixing of the medicament.
- 4.1.18 After proper mixing of the medicament connect the bottom discharge valve of the Medicament Mixing Unit with lobe pump inlet valve and outlet valve of lobe pump to inlet valve of the homogenizer.
- 4.1.19 Connect the out let valve of the Homogenizer with inlet valve of Medicament Mixing Unit on the lid. And re-circulate the medicament through lobe pump, homogenizer to Medicament Mixing Unit with continue stirring as per instruction of the BMR.
- 4.1.20 The Homogenizer is used for the uniform mixing of medicament powder, liquid and semi solids. It forms a Homogenous mixture.
- 4.1.21 After proper mixing of the medicament, use sieve on the Vibro Sifter for shifting of the medicament as per the description of the BMR.
- 4.1.22 After shifting of the medicament transfer the medicament into the Medicament Mixing Unit and apply the vacuum for de-aeration process to remove entrapped air.
- 4.1.23 Push "UP" button to lift up the medicament mixing unit lid.
- 4.1.24 Open the bottom discharge valve of the Medicament Mixing Unit and transfer the medicament into medicament holding tank.
- 4.1.25 Rinse the inner surface of the medicament mixing vessel, SS transfer pipe, lobe pump, Homogenizer with used vehicles of medicament.



### STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (Soft Gel)	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Medicament Mixing Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 4.1.26 Switch "OFF" the main supply of Medicament Mixing Unit after batch completion.
- 4.1.27 Enter the operation complete time in equipment usage log book as per SOP.
- 4.1.28 Remove "STATUS LABEL" and affix the "TO BE CLEANED" label on the equipment with duly filled and signature of production officer.
- 4.1.29 Update the "AREA STATUS BOARD" with duly filled and signature of production officer.

#### **4.2 Precaution**

- 4.2.1 Do not run the Medicament Mixing Unit in without any material.
- 4.2.2 Discharge valve shall be closed before starting the operation.
- 4.2.3 Never leave the Medicament Mixing Unit with material overnight.

#### **4.3 CLEANING PROCEDURE**

##### **4.3.1 Cleaning procedure Type A**

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

- 4.3.1.1 Remove "TO BE CLEANED" label and affix "UNDER CLEANING" label to the machine with date and signature of the production officer as per SOP.
- 4.3.1.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.3.1.3 Switch "ON" the main electric supply of the medicament mixing unit from electric panel.
- 4.3.1.4 Push "UP" button to lift up the Medicament Mixing Unit lid.
- 4.3.1.5 Inside of the Medicament Mixing Unit wipe out with vehicle (vehicle is the oil in which the medicament has been prepared).
- 4.3.1.6 Then clean the outer and inner parts with dry lint free cloth.
- 4.3.1.7 Wipe with clean lint free cloth with 70% v/v IPA solution.
- 4.3.1.8 Clean the area as per SOP.
- 4.3.1.9 Replace the "UNDER CLEANING" status label with "CLEANED" status label with date and signature of the Production Officer.
- 4.3.1.10 Record the cleaning complete time in equipment usage log book as per SOP.

##### **4.3.2 Cleaning procedure Type B**

**This is a cleaning procedure for change over of product with different active/ colour/ descending potency or after maintenance of contact parts.**



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production (Soft Gel)	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Medicament Mixing Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- 4.3.2.1 Replace the “TO BE CLEANED” status label with “UNDER CLEANING” status label with date and signature of the Production officer and enter cleaning time in log book.
- 4.3.2.2 Enter the cleaning start time in equipment usage log book as per SOP.
- 4.3.2.3 Switch “ON” the main electric supply of the Medicament Mixing Unit from electric Panel.
- 4.3.2.4 Push “UP” button to lift up the Medicament Mixing Unit lid.
- 4.3.2.5 Remove the below medicament mixing unit and transfer to the washing area.
- 4.3.2.6 Push “DOWN” button to Down the Medicament Mixing Unit lid.
- 4.3.2.7 Dismantle the stirrer from the lid, SS outlet medicament pipe and clamps. All these keeps on the SS pallet and transfer to the washing area with trolley.
- 4.3.2.8 All parts rinse with purified water to completely remove adhered medicament. Then clean with 1.0% v/v Teepol solution for properly cleaning of traces of medicament and oil.
- 4.3.2.9 Clean the Medicament Mixing Unit lid with purified water and 1.0% v/v Teepol solution for properly cleaning of traces of medicament and oil.
- 4.3.2.10 Finally all parts wash with sufficient purified water to clean the trace of the Teepol solution.
- 4.3.2.11 Dry the stirrer, lid, SS outlet pipe and Medicament Mixing Unit with compressed air and dry lint free cloth.
- 4.3.2.12 Use 70 % v/v IPA solution with dry lint free cloth moping of all the cleaned parts.
- 4.3.2.13 Assemble the stirrer, SS medicament pipe and clamps to Medicament Mixing Unit lid.
- 4.3.2.14 Push “UP” button to lift up the Medicament Mixing Unit lid.
- 4.3.2.15 Fix the medicament mixing unit below to the Medicament Mixing Unit lid and down it on.
- 4.3.2.16 Switch “OFF” the main power supply.
- 4.3.2.17 Clean the area as per SOP No. PRD/003.
- 4.3.2.18 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of the Production Officer.
- 4.3.2.19 Record the cleaning complete time in equipment usage log book as per SOP.

**5.0 ANNEXURE (S) :**  
Nil



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (Soft Gel)	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Medicament Mixing Unit	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 6.0 REFERENCE (S):

SOP: Procedure of filling of equipment log book.

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

### 7.0 ABBREVIATION (S) / DEFINITION (S):

BMR : Batch Manufacturing Record

IPA : Iso Propyl Alcohol

v/v : Volume/Volume

ML : Milliliter

SS : Stainless Steel

NA : Not Applicable

### REVISION CARD

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