



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Gelatin Mass Colour Mixer	<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 a Procedure for Operation and Cleaning of Gelatin Mass Colour Mixer.

### 2.0 SCOPE:

This SOP is applicable to Operation and Cleaning of Gelatin Mass Colour Mixer used in Soft Gelatin Capsule Section.

### 3.0 RESPONSIBILITY:

Officer / Executive – Production

### 4.0 ACCOUNTABILITY:

Head – Production

### 5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
LTD.	Limited
OSD	Oral Solid Dosage
PVT.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

#### 6.1 OPERATION:

- 6.1.1 Check & ensure that colour mixer is cleaned properly.
- 6.1.2 Take the line clearance from QA as per “Line Clearance” SOP and enter the details in BMR.
- 6.1.3 Affix the status label on the colour mixer.
- 6.1.4 Lift the colour mixer manually.
- 6.1.5 Take the gelatin mass tank having gel mass under the colour mixer.
- 6.1.6 Add the colour solution to gel mass.
- 6.1.7 Switch “ON” the colour mixer and start the mixing.
- 6.1.8 After completion of the mixing switch “OFF” the colour mixer.
- 6.1.9 Enter the operation details in “Machine Utilization Record”

#### 6.2 CLEANING:

- 6.2.1 Ensure that mains switch is “OFF”.



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- 6.2.2** Wash the colour mixer with potable water and collect the wash water in a container and drain it to washing area.
- 6.2.3** Wash the colour mixer using 2 % v/v Extran MA-02 solution with the help of nylon brush and collect the wash water in a container and drain it to the washing area.
- 6.2.4** Again wash the colour mixer with potable water and drain it to the washing area.
- 6.2.5** Finally wash the colour mixer with purified water and drain it to the washing area.
- 6.2.6** Dry the colour mixer using dry lint free cloth.
- 6.2.7** Mop the colour mixer with 70% v/v IPA solution.
- 6.2.8** Cleaning step 6.2.1 to 6.2.10 shall be performed if the Cleaned equipment kept idle more than 72 hrs.
- 6.2.9** Cleaning step 6.2.1 to 6.2.10 shall be performed if the Dirty equipment kept idle more than 24 hrs.
- 6.2.10** Deviation shall be logged if the equipment shall be exceed from the defined hold time i.e. 72 hrs. for Cleaned Equipment's and 24 hrs. for dirty Equipment's.
- 6.2.11** Swab/Rinse sample shall be send for testing and equipment shall be used, after once the result obtained satisfactory.
- 6.2.12** Affix a label as "**Cleaned**".
- 6.2.13** Enter the cleaning details in "Machine Utilization Record".

**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:**

Not Applicable.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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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