PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Operation and Cleaning of Planetary Mixer	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Planetary Mixer.

2.0 SCOPE:

This SOP is applicable to Operation & Cleaning of Planetary 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
IPA	Isopropyl Alcohol
Ltd.	Limited
PLM	Planetary Mixer
Pvt.	Private
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure that the equipment & area is cleaned.

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 machine.

6.1.4 Ensure that the temperature and humidity of area is within limit as specified in BMR.

6.1.5 Switch ‘ON’ the PLM and lift the stirrer by turning the Knob switch anticlockwise to up position.

6.1.6 Load the medicament in PLM Bowl.

6.1.7 Take the PLM Bowl below stirrer and adjust the position.

6.1.8 Take down the stirrer by turning the knob switch clockwise direction to down position.

6.1.9 Switch ‘ON’ the stirrer by pressing the slow/fast push button and set the time on timer as

specified in BMR.

6.1.10 Switch 'ON' the vacuum pump and open the vacuum valve upto 650 to 715 mm/Hg for de-aeration of medicament or as defined in BMR.

6.1.11 After completion of mixing switch 'OFF' the stirrer by pressing "Red" push button.

6.1.12 Open the vacuum valve and release the vacuum.

6.1.13 After completion of process lift the stirrer by turning the Knob switch anticlockwise to up position.

6.1.14 Take out the PLM bowl from the PLM.

6.1.15 Enter the operation details in "Machine Utilization Record"

6.2 CLEANING:

6.2.1 For Product Changeover (Type B Cleaning):

6.2.1.1 Ensure that mains switch is "OFF".

6.2.1.2 Dismantle the stirrer and PLM Bowl of PLM and take to washing area.

6.2.1.3 Clean it with 2 %v/v of Extran MA-02 solution.

6.2.1.4 Wash with sufficient quantity of potable water.

6.2.1.5 Finally rinse with sufficient quantity of purified water.

6.2.1.6 Wipe the stirrer and PLM Bowl with dry lint free cloth and finally mop with 70% v/v IPA solution.

6.2.1.7 Put the stirrer in a SS tray.

6.2.1.8 Officer/Executive QA shall check visually & collect the swab sample with intimation slip cum analysis report and send to QC for analysis.

6.2.1.9 Use the PLM after receiving swab test intimation slip cum analysis report from QC showing negative identification.

6.2.1.10 Assemble the stirrer in PLM.

6.2.1.11 Clean the remaining part of PLM with the help of wet cloth followed by lint free cloth.

6.2.1.12 Mop the PLM with 70% v/v IPA solution.

6.2.1.13 Affix a label as "Cleaned" on the PLM.

6.2.1.14 Enter the cleaning details in "Machine Utilization Record"

6.2.2 For Batch Changeover (Type A Cleaning) :

6.2.2.1 Clean the PLM by mopping with dry lint free cloth.

6.2.2.2 Mop the PLM with 70% v/v IPA solution.

6.2.2.3 Affix the status label on the PLM.

6.2.2.4 Enter the cleaning details in "Machine Utilization Record".

6.2.3 Frequency of Cleaning:

6.2.3.1 For B Type Cleaning:

(a) Product to Product Changeover.

(b) After 5 batches of the same product.

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

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

(e) After any Maintenance of Product Contact Parts.

(f) Changeover of one Batch to Next Batch of the same Product with Descending Potency.

6.2.3.2 For A Type Cleaning:

(a) Changeover from one Batch to Next Batch of the same Product with Same Potency.

(b) Changeover from one batch to next Batch of the same Product with Higher Potency.

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.

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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