



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Gelatin Mass Holding Tank	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Gelatin Mass Holding Tank.

2.0 SCOPE:

This SOP is applicable to Operation & Cleaning of Gelatin Mass Holding Tank used in Soft Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

°C	Degree Centigrade
BMR	Batch Manufacturing Record
IPA	Isopropyl Alcohol
Ltd.	Limited
OSD	Oral Solid Dosage
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
v/v	Volume by volume

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure that the area and gelatin mass holding tank is clean.

6.1.2 Officer/Executive Production shall check the water level in the jacket of gelatin mass holding tank.

6.1.3 Switch “ON” the heater of gelatin mass holding tank and set the heating temperature $55\pm 5^{\circ}\text{C}$ as specified in BMR.

6.1.4 Unload the gelatin mass to the pre heated gelatin mass holding tank.

6.1.5 Record the temperature of gel mass in gelatin mass holding tank hourly during holding of gelatin mass in the tank as per **Annexure-I “Gelatin Mass Holding Tank - Temperature Record”**.

6.1.6 Enter the operation details in “Machine Utilization Record”

6.2 CLEANING:



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Gelatin Mass Holding Tank	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.2.1** Check & ensure that heater of gelatin mass holding tank is “OFF”
- 6.2.2** Transfer the gelatin mass holding tank to the washing area.
- 6.2.3** Fill the hot water in gelatin mass holding tank, leave it as such for remove the traces of previous gelatin mass.
- 6.2.4** Clean the gelatin mass holding tank with the help of nylon brush and drain it to the washing area.
- 6.2.5** Visually check the tank for traces of gelatin mass, if there again repeat the point **6.2.3** to **6.2.4**.
- 6.2.6** Wash the gelatin mass holding tank with sufficient quantity of potable water.
- 6.2.7** Finally rinse the gelatin mass with sufficient quantity of purified water.
- 6.2.8** Dry the gelatin mass holding tank with dry compressed air.
- 6.2.9** Take the gelatin mass holding tank to the respective area.
- 6.2.10** Mop the tank with 70% v/v IPA solution.
- 6.2.11** Cleaning step 6.2.1 to 6.2.10 shall be performed if the Cleaned equipment kept idle more than 72 hrs.
- 6.2.12** Cleaning step 6.2.1 to 6.2.10 shall be performed if the Dirty equipment kept idle more than 24 hrs.
- 6.2.13** Deviation shall be logged if the equipment shall be exceed from the defined hold time i.e. 72 hrs. for Cleaned Equipment and 24 hrs. for dirty Equipment.
- 6.2.14** Affix the label as “Cleaned”
- 6.2.15** Enter the cleaning details in “Machine Utilization Record”

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
ANNEXURE-I	Gelatin Mass Holding Tank - Temperature Record”.	

ENCLOSURES: SOP Training Record



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Gelatin Mass Holding Tank	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

8.0 DISTRIBUTION:

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

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

