



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Gelatin Melting Reactor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the Procedure for Operation & Cleaning of Gelatin Melting Reactor.

2.0 SCOPE:

This SOP is applicable for Operation & Cleaning of Gelatin Melting Reactor used in Soft Gelatin Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

^o C	Degree Centigrade
BMR	Batch Manufacturing Record
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SS	Stainless Steel

6.0 PROCEDURE:

6.1 OPERATION:

- 6.1.1 Ensure that Gelatin Melting Reactor is cleaned and the bottom valve is closed.
- 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 reactor.
- 6.1.4 Open the hot water valve of Gelatin Melting Reactor.
- 6.1.5 Allow to reach the temperature up to 70^oC.
- 6.1.6 Open the lid of Gelatin Melting Reactor and load the liquid materials to the gelatin melting reactor as per specified in respective BMR.
- 6.1.7 Load the gelatin and preservatives to step 6.1.4 as specified in respective BMR and close the lid.
- 6.1.8 Switch "ON" the stirrer and maintain the temperature of Gelatin Melting Reactor till to 70^oC or as specified in respective BMR.



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- 6.1.9 Add the Rest materials i.e., ethyl vanillin to the step 6.1.6 as specified in respective BMR.
- 6.1.10 Open the vacuum valve for de-aeration of gelatin mass till the 500-600 mm/Hg or as per specified in respective BMR.
- 6.1.11 After completion of de-aeration close the vacuum valve and release the vacuum by operating the outlet vacuum valve.
- 6.1.12 Take the sample of gelatin mass through bottom valve in a SS tray.
- 6.1.13 Ensure that there is no air bubbles in gelatin mass.
- 6.1.14 Unload the gelatin mass in preheated gelatin holding tanks through the nylon sieve as specified in respective BMR.
- 6.1.15 Enter the operation details in "Machine Utilization Record."

6.2 CLEANING:

- 6.2.1 Fill the Gelatin Melting Reactor tank with approximate 550 liter potable water.
- 6.2.2 Heat the water up to 60-70°C (Approximate time taken to attain 60-70°C is 1 hour 30 minute) with continuous stirring.
- 6.2.3 Ensure that gel mass traces are completely melted and removed from the inner surfaces of the tank.
- 6.2.4 Drain out the whole filled potable water through the bottom valve previously taken up approximate 550 liter.
- 6.2.5 Taken up 10 liter potable water into the gelatin melting reactor tank for scrubbing the inner and outer surface of Gelatin Melting Reactor for 30 min and then drain out through bottom valve of Gelatin Melting Reactor.
- 6.2.6 Taken up 35 liter Potable water into the Gelatin Melting Reactor Tank for wash the inner and outer surface of Gelatin Melting Reactor for 30 min and then drain out through bottom valve of Gelatin Melting Reactor.
- 6.2.7 Clean the Outer surface of Tank with potable water, use nylon brush for cleaning.
- 6.2.8 Finally rinse the reactor with 20 liter purified water, wipe the tank surface with dry clean Lint free Cloth.
- 6.1.1 Close the bottom valve and affix "Cleaned" label.
- 6.1.2 Enter the cleaning details in "Machine Utilization Record".

Note: Cleaning time of Gelatin Melting Reactor may vary on the basis of availability of cleaning operator.



PHARMA DEVILS

PRODUCTION DEPARTMENT

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POTABLE AND PURIFIED WATER USED QUANTITY	
CYCLE-1	550 Ltr.
CYCLE-2	10 Ltr.
CYCLE-3	35 Ltr.
CYCLE-4	20 Ltr.

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

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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