



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Operation and Cleaning of Liquid Manufacturing Tank 2000 Ltr.	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Liquid manufacturing tank 2000 Ltr.

2.0 SCOPE:

This SOP is applicable to Operation and Cleaning of Liquid manufacturing tank in Ointment Section.

3.0 RESPONSIBILITY:

Production- Officer / Executive.

4.0 ACCOUNTABILITY:

Head- Production

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
IPQA	In-Process Quality Assurance
RM	Raw Material
SOP	Standard Operating Procedure
RH	Relative Humidity
VFD	Variable frequency Drive
RM	Raw Material
Hrs	Hours
SS	Staleness steel

6.0 PROCEDURE:

6.1 GENERAL REQUIREMENT:

6.1.1 Check the cleanliness of Liquid manufacturing tank.

6.1.2 Check the “CLEANED” status label on Liquid manufacturing tank.

6.1.3 Ensure that the Environmental Conditions are as per specification in BPCR and enter the same into BPCR as well as in Environmental Monitoring Record (Temperature NMT 25°C & RH NMT 65%).

6.1.4 Remove the “CLEANED” status label from Equipment and place Equipment “INPROCESS STATUS” label on it. Line Clearance from IPQA.

6.2 OPERATION:



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6.2.1 Switch “ON” the Main power supply of Liquid manufacturing tank.

6.2.2 Set the speed in VFD of Liquid manufacturing tank as per requirement.

6.2.3 Start the mixing of RM by Stirrer.

6.2.4 After completion of Batch transfer into holding tank.

6.2.5 Switch “OFF” the stirrer after completion of the Batch and affix a “TO BE CLEANED” status label on it.

6.2.6 Make an entry of Operation Time in BPCR and “Equipment Log”.

6.3 CLEANING:

6.3.1 A Type Cleaning (Batch to Batch & Sift End Cleaning):

6.3.1.1 Ensure that the External Liquid manufacturing tank shall have “TO BE CLEANED” status label.

6.3.1.2 Remove the “TO BE CLEANED” status label

6.3.1.3 Wash the External Liquid manufacturing tank with Purified Water.

6.3.1.4 Dry mop the External Liquid manufacturing tank with Lint Free cloth on outer surface.

6.3.1.5 Affix a “CLEANED” status label on the External Liquid manufacturing tank.

6.3.1.6 Make an entry of Cleaning Time in “Equipment Log”.

6.3.1.7 A - Type Cleaning is to be done.

- Batch to Batch changeover of the same product.
- Change over to higher strength of same colour.
- At the end of the Shift.

6.3.2 B Type Cleaning (Product to Product Cleaning)

6.3.2.1 Ensure that the External Liquid manufacturing tank shall have “TO BE CLEANED” status label.

6.3.2.2 Remove the “TO BE CLEANED” status label.

6.3.2.3 Wash and Flush the External Liquid manufacturing tank with Hot Purified Water.

6.3.2.4 Use Extran MA 02 solution 2% v/v. after finally rinse three times with purified water.

6.3.2.5 Dry mop the External Liquid manufacturing tank with lint free cloth on outer surface.

6.3.2.6 Affix a “CLEANED” status label on the External Liquid manufacturing tank.



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6.3.2.7 Make an Entry of Cleaning Time in “**Equipment Log**”.

6.3.2.8 B-Type Cleaning is to be done.

- After 48 hrs. of type A-Type cleaning.
- Product Change Over.
- Change over to Lower strength of same product.
- After maintenance or major breakdown.
- Change over to upper strength with different colour.
- If the Equipment is not used within 72 hrs. clean the equipment before use.
- After every 5 batches of same product in case of campaign product.

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:

Machine –Manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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