



STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Cleaning & Sanitization of Holding Vessels	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Cleaning and Sanitization of Holding Vessels.

2.0 SCOPE:

This SOP is Applicable for Cleaning and Sanitization of Holding Vessels in Ointment Section.

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BPCR	Batch Production and Control Record
IPQA	In-Process Quality Assurance
No.	Number
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 CLEANING:

6.1.1 Type-A Cleaning (Batch to Batch):

6.1.1.1 Ensure that the Equipment has a “TO BE CLEANED” Status Label.

6.1.1.2 Previous Product removes from Holding Vessel with Purified Water.

6.1.1.3 Wash and flush the Holding Vessel with Hot Purified Water.

6.1.1.4 Dry the Holding Vessel with Compressed Air.

6.1.1.5 Affix a “CLEANED” Status Label on the Vessel.

6.1.1.6 Make an entry of Cleaning Time in Equipment Log, in **Reference SOP**.

6.1.1.7 Type- A Cleaning is to be done.

6.1.1.7.1 Batch to Batch changeover of the same Product.

6.1.1.7.2 Change over to higher strength of same Colour.

6.1.2 Type- B Cleaning (Product to Product Cleaning)

6.1.2.1 Ensure that the Equipment has a “TO BE CLEANED” Status Label on it.



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- 6.1.2.2 Previous Product removes from Holding Vessel with Purified Water.
- 6.1.2.3 Dismantle all parts of Holding Vessel.
- 6.1.2.4 Clean the parts with Hot Purified Water & elaborate for removal of Extran MA 02 solution 2% v/v, after that rinse with hot purified water.
- 6.1.2.5 Wash and flush the Holding Vessel with Hot Purified Water.
- 6.1.2.6 Collect the cleaned dry parts and assemble them.
- 6.1.2.7 Re-wash and Flush the Holding Vessel with Hot Purified Water.
- 6.1.2.8 Ensure the cleanliness of Holding Vessel visually.
- 6.1.2.9 Affix a “CLEANED” Status Label on the Vessel.
- 6.1.2.10 Make an entry of Cleaning Time in Equipment Log. In **Reference SOP.**
- 6.1.2.11 **Type-B Cleaning is to be done:**
- 6.1.2.12 After 48 hrs of type-A Cleaning.
- 6.1.2.13 Product Change Over.
- 6.1.2.14 Change over to Lower strength of same Product.
- 6.1.2.15 After Maintenance or major Breakdown.
- 6.1.2.16 Change over to upper strength with different Color.
- 6.1.2.17 If the Equipment is not used within 72 hours, clean the Equipment before use.
- 6.1.2.18 After every 5 Batches of same Product in case of campaign Product.

6.2 HOT WATER SANITIZATION:

- 6.2.1 Hot water Sanitization of Holding Vessel after type-B cleaning to be done.
- 6.2.2 Collect the Hot Purified Water up to 80°C - 85°C into the Holding Vessels and Hold for 15 Minutes.
- 6.2.3 Drain the Hot Purified Water after Sanitization Process.
- 6.2.4 Affix the “CLEANED” status label on the Holding Vessels.
- 6.2.5 Make an entry in Vessels Sanitization Record as shown in **ANNEXURE-I.**



PHARMA DEVILS

PRODUCTION DEPARTMENT

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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Holding Vessels Sanitization Record	

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

