



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production (External Preparation)	SOP No.:
Title: Procedure for Cleaning of Containers, Utensils and Sampling Rod	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Cleaning of Containers, Utensils and Sampling Rod.

2.0 SCOPE:

This SOP is applicable for Cleaning of Containers, Utensils and Sampling Rod in Production Department.

3.0 RESPONSIBILITY:

Production Officer/Executive: Ensure Cleaning of container and utensils.

IPQA Officer/Executive: Ensure Cleaning of Sampling Rod.

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

IPQA	In-Process Quality Assurance
IPA	Isopropyl Alcohol
SS	Stainless Steel
SOP	Standard Operating Procedure
Pvt.	Private
Ltd.	Limited
%	percent
v/v	volume by volume

6.0 PROCEDURE:

- 6.1 Ensure that the SS Containers, Utensils and sampling rod has a **“TO BE CLEANED”** Status label on it.
- 6.2 Remove the **“TO BE CLEANED”** label from the SS Containers, Utensils and sampling rod.
- 6.3 Wash the SS Containers, Utensils and sampling rod with hot Purified water until removing of previous residue.
- 6.4 Pouring/ Scrubbing of Extran MA 02 solution 2% v/v inside and outside of SS Containers, Utensils and sampling rod.
- 6.5 Again wash with hot purified water till remove the trace of Extran MA 02 solution 2% v/v.
- 6.6 After that dry of SS containers, Utensils & sampling rod with compressed air or 70% IPA.
- 6.7 Ensure the cleanliness of SS Containers, Utensils and sampling rod visually.
- 6.8 Affix a **“CLEANED”** status label on SS Containers, Utensils and sampling rod.



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- 6.9** Use the cleaned SS Containers, Utensils and sampling rod within 120hrs after cleaning. If the utensils does not used within 120 hrs. then clean the utensils before use.
- 6.10** The acceptance criteria - Rinse water/swab analysis is performed and the resultant sample is scanned under UV light. That should not be more than 0.023.
- 6.11** Maintain the cleaning record of containers, utensils and sampling rod as format shown as **Annexure-I**.
- 6.12** If any discrepancy is found in accessories like rusting, cracking, damage, unfit for use, it shall be removed from area immediately and look for new or any other alternate for the same.
- 6.13** Accessories like Scoops, Ladle, Spatula, Spoon, Measuring Cylinder, Sampling Rod or other items shall be reviewed against the master list every six months by concerned department and QA to verify their fitness for intended purpose as per **Annexure-II**.

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT NO.
Annexure-I	Record For Cleaning of Containers, Utensils and sampling rod	
Annexure-II	Check list for Verification of Containers, Utensils and Sampling Rod	

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



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ANNEXURE – II

CHECK LIST FOR VERIFICATION OF CONTAINERS, UTENSILS AND SAMPLING ROD

Frequency: Six Month	BLOCK :
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S.No.	Name of Containers, Utensils and Sampling Rod	Verify Status OK/ NOT OK	Checked By (User Department)	Verified By QA
1.	Scoop			
2	Spoon Small/Big			
3.	Spatula			
4.	Sampling Rod			
5.	Measuring Cylinder			
6.	Measuring Cylinder			
7.	SS Container			
8.	SS Container			
9.	SS Container			
10.	SS Container			
11.	SS Container			