



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning & Handling of Silicon Tubes

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To lay down the procedure for Cleaning & Handling of Silicon Tubes.

2.0 SCOPE:

This SOP is applicable for Cleaning & Handling of Silicon Tubes and to ensure that such are handled before and after filling in proper manner in to the Production area at

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 NUMBERING SYSTEM OF SILICON TUBING:

6.1.1 Each set of Silicon Tubes shall have unique identification number and control by purpose and generic product wise. Once a number is allocated to any set of silicon tubes shall not be repeated to any other set of silicon tubes.

6.1.2 Enter the receipt detail of silicon tube with ID No. shown in **Annexure-I**.

6.1.3 Each set shall be consist of 9 alphanumeric characters (5 alphabets, 1 separator & 3 numeric).

For Example: TPWST-001

TP : Represent Three Piece Line

WST : Represent WFI Silicon Tube

- : Separator



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Department: Production	SOP No.:
Title: Cleaning & Handling of Silicon Tubes	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

001 : Represent the Serial Number

6.1.4 Prepare Silicon Tube Status Label as per format shown in **Annexure-II**.

6.2 CLEANING OF SILICON TUBE:

6.2.1 Before use of fresh Silicon tubing used for the product filling shall be send for washing and sterilization room through pass box in washing area.

6.2.2 Wash and rinse the Silicon Tube with sufficient quantity of purified water.

6.2.3 After that wash and rinse the Silicon Tubing with sufficient quantity of water for Injection (WFI) followed by dry the silicon tube with 0.2 μ filtered compressed air.

6.3 HANDLING AND STORAGE OF SILICON TUBE:

6.3.1 Issued the silicon tube as per the requirement.

6.3.2 After cleaning & sterilization of silicon tube unload under LAF and transfer through mobile LAF to aseptic filling area for assembling.

6.3.3 After completion of filling & sealing activity, transfer the silicon tube to the pre wash room, cleaned the silicon tube and dry with air & return to storage area.

6.3.4 Wrap the both end of tubes with parchment paper and keep in double polybag with proper status label in respective SS locker.

6.3.5 Discard the silicon tube after use of 30 sterilization cycle or whenever any change in colour or damage.

6.4 Usages of silicon tubes shall be recorded as per format Shown in **Annexure-III**.

7.0 ABBREVIATION:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number



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Department: Production	SOP No.:
Title: Cleaning & Handling of Silicon Tubes	Effective Date:
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Issue Date:	Page No.:

WFI	Water for injection
LAF	Laminar Air Flow
SS	Stainless steel
QA	Quality Assurance

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	List of Silicon Tube	
Annexure-II	Identification Tag	
Annexure-III	Silicon Tube Log Book	

9.0 DISTRIBUTION:

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

10.0 REFERENCES:

Not Applicable

11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



PHARMA SCHOLARS

PRODUCTION DEPARTMENT

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ANNEXURE – II

SILICON TUBES STATUS LABEL

SILICON TUBES STATUS LABEL	
Generic Product Name	
ID No	
Location	

