



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Handling and Usage of Silicon Tubes

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
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1.0 OBJECTIVE:

To lay down the procedure for Handling and Usage of Silicon Tubes.

2.0 SCOPE:

This SOP is applicable for Handling of Silicon Tubes Used for Filling of Sterile Solution w.r.t. Preparation, Numbering system, usage, cleaning, verification & destruction in DPI, Ampoule, Three piece line of Production department (Aseptic area).

3.0 RESPONSIBILITY:

Operating Person: Production

4.0 ACCOUNTABILITY:

Head-Production

5.0 ABBREVIATIONS:

ID	Identification
LAF	Laminar Air Flow
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
SS	Stainless Steel
WFI	Water For Injection
I.D.No	Identification Number
B.No	Batch Number
Sign	Signature
IPQA	In Process Quality Assurance
ST	Silicon tube

6.0 PROCEDURE:

- 6.1 Each set of Silicon Tubes shall have unique identification number and control by generic product wise.
- 6.2 Once a number is allocated to any set of silicon tubes shall not be repeated to any other set of silicon tubes.
- 6.3 Silicone tube set of each product shall be stored in respective area and maintain the list of same as per **Annexure-I** Titled as “**Product wise List of Silicon Tubes Set**”.
- 6.4 For detail of silicon tube set w.r.t the dimension, length, Nos of tube, Location during use and ID No and pictorial representation refer Annexure of respective line.
- 6.5 Status label shall be affix on each product silicone tube set for proper segregation as per **Annexure-II** Titled as “**Silicon Tubes Status Label**”.



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- 6.6** Issued the silicon tube as per product requirement and details of Issuance, Sterilization & Destruction shall be maintained as per **Annexure-III** titled as “**Issuance, Sterilization & Destruction Record of Silicon Tubes set**”.
- 6.7** Before use of fresh Silicon tubing used for the product filling shall be cleaned as per SOP, in respective cleaning area.
- 6.8** After used of silicone tube set shall be cleaned as per SOP and dry with compressed air.
- 6.9** Wrap the dried silicon tubes with bio barrier paper and keep in designated decron bag/SS container having identification label as per **Annexure -II**.
- 6.10** Keep this bag/container in the designated storage area.
- 6.11** **Destruction of Silicon tube:** Discard the silicon tube after use of 25 sterilization cycle /After 6 Month/Any discrepancy in physical appearance which is earlier and shall be record the same in **Annexure-III**.
- 6.12** **Procedure for destruction-** Cut the silicon tube into pieces and transfer them in polybag. Tie the bag with cable tie and labelled it as “Rejected” as per SOP. Transfer the polybag to scrap.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Product wise List of Silicon Tubes Set	
Annexure-II	Silicon Tubes Status Label	
Annexure-III	Issuance, Sterilization & Destruction Record of Silicon Tubes set	
Annexure-IV	Silicon Tube Set Detail and Pictorial Representation of Three Piece	
Annexure-V	Silicon Tube Set Detail and Pictorial Representation of Ampoule line	
Annexure-VI	Silicon Tube Set Detail and Pictorial Representation of DPI line	

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:

- SOP: Status Labelling



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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

SILICON TUBES STATUS LABEL	
Generic Product Name	
ID No	
Location	



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ANNEXURE-III

ISSUANCE, STERILIZATION & DESTRUCTION RECORD OF SILICON TUBES SET

Block		Section	
Generic Name of Product		ID No. of Silicon tube set	
Date of issue		Proposed discard Date	
		Checked by:	

Frequency of Destruction: After 25 sterilization cycle /After 6 Month/Any discrepancy in physical appearance which is earlier.

Sterilization Cycle Record					
Cycle No.	1	2	3	4	5
Autoc. Load No.					
SFG Batch No.					
Physical Status					
Sign/Date					
Cycle No.	6	7	8	9	10
Autoc. Load No.					
SFG Batch No.					
Physical Status					
Sign/Date					
Cycle No.	11	12	13	14	15
Autoc. Load No.					
SFG Batch No.					
Physical Status					
Sign/Date					
Cycle No.	16	17	18	19	20
Autoc. Load No.					
SFG Batch No.					
Physical Status					
Sign/Date					
Cycle No.	21	22	23	24	25
Autoc. Load No.					
SFG Batch No.					
Physical Status					

Destruction done By(Production)	
Checked By(Production)-Sign/Date	
Verified By(IPQA)-Sign/Date	

Sign/Date



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ANNEXURE-IV SILICON TUBE SET DETAIL AND PICTORIAL REPRESENTATION OF THREE PIECE

1. Silicon Tube Set Detail:

Silicon tube set	Dimension	Length (Approx.)	No. of tube in set	Location during use	ID No. of silicone tube set
For filling machine parts	10 x 18 mm	2300 mm	01 No	Between filling vessel & manifold	TIST-NNN Where : TI: Three piece ST : Silicone Tube NNN: Serial No. For example :
		250 mm	06 Nos	Between manifold & connector	
	6 x12 mm	500 mm	03 Nos	Between Connector & disc filter	
		600 mm	06 Nos	Between connector & filling nozzle	
		2000 mm	01 No	Between nozzle & filling vessel	
		150 mm	03 Nos.	Between disc filter & connector	
	3 x 6 mm	400 mm	06 Nos.	Between disc filter & pre nitrogen nozzle	
		400 mm	06+01 Nos.	Between disc filter & post nitrogen nozzle	
For Disinfectant filtration	10 x 18 mm	2000 mm	01 No	Between pressure vessel & filter housing.	
		2000 mm	01 No	Between filter housing & SS container	
		2000 mm	01 No.	Between Nitrogen line to pressure vessel	
		1500 mm	01 No.	Between WFI line to pressure vessel.	

2. Pictorial Representation of Silicon Tube Set of Machine Parts:



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3. Pictorial Representation of Silicon Tube Set of Disinfectant filtration:





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ANNEXURE-V SILICON TUBE SET DETAIL AND PICTORIAL REPRESENTATION OF THREE PIECE

1. Silicon Tube Set Detail:

Silicon tube set	Dimension	Length (Approx.)	No. of tube in set	Location during use	ID No. of silicone tube set
For filling machine parts	10 x 18 mm	200 mm	12 Nos	Between manifold & connector	TQST-NNN Where : TQ: Three piece ST : Silicone Tube NNN: Serial No. For example:
		2500 mm	01 No	Between filling vessel & manifold	
	6 x 12 mm	100 mm	02 Nos	Between nozzle & disc filter	
		600 mm	12 Nos	Between connector & filling nozzle	
		2000	01 No	Between nozzle & filling vessel	
	3 x 6 mm	900 mm	01 No	Between disc filter & Pre nitrogen nozzle	
1500 mm		01 No	Between disc filter to Post nitrogen nozzle		
For Disinfectant filtration	10 x 18 mm	2500 mm	01 No	Between pressure vessel & Filter housing.	
		1300 mm	01 No	Between Filter housing & SS container	

2. Pictorial Representation of Silicon Tube Set of Machine Parts:



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3. Pictorial Representation of Silicon Tube Set of Disinfectant filtration:





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ANNEXURE-VI

SILICON TUBE SET DETAIL AND PICTORIAL REPRESENTATION OF AMPOULE LINE

1. Silicon Tube Set Detail:

Silicon tube set	Dimension	Length (Approx.)	No. of tube in set	Location during use	ID No. of silicone tube set
For filling machine parts	15 x 20 mm	900 mm	01 Nos	Buffer tank to Solution Manifold	AMST-NNN Where : AM: Ampoule ST : Silicone Tube NNN: Serial No. For example :
	6 x 10 mm	600mm	12 Nos	Solution manifold to Connector	
	4 x 8 mm	100 mm	12 Nos	Connector to filling pump	
	4 x 8 mm	600 mm	12 Nos	Filling pump to solution Nozzle	
	4 x 8 mm	600mm	12 Nos	Manifold outlet to pre Nitrogen nozzles	
	4 x 8 mm	600mm	12 Nos	Manifold outlet to post Nitrogen nozzles	
For Disinfectant filtration	10 x 18 mm	3500 mm	01 No	Between pressure vessel & Filter housing.	
		2500 mm	01 No	Between Filter housing & SS container	

2. Pictorial Representation of Silicon Tube Set of Machine Parts:



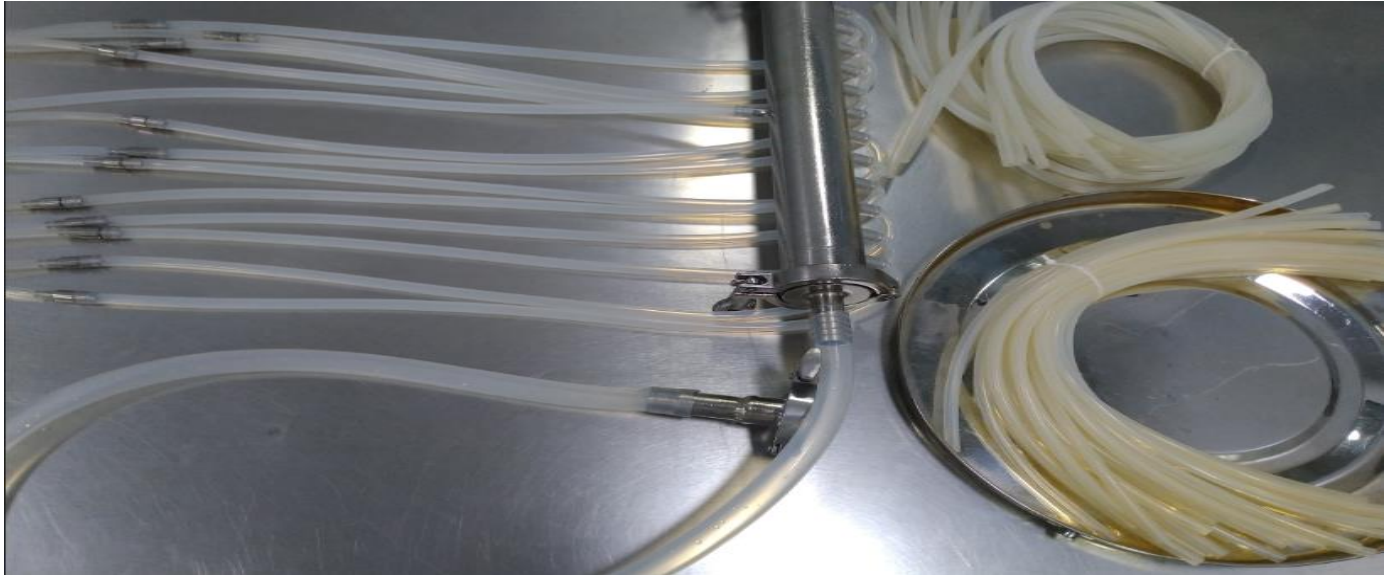
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3. Pictorial Representation of Silicon Tube Set of Disinfectant filtration:





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ANNEXURE-VII

SILICON TUBE SET DETAIL AND PICTORIAL REPRESENTATION OF DPI LINE

1. Silicon Tube Set Detail:

Silicon tube set	Dimension	Length (Approx.)	No. of tube in set	Location during use	ID No. of silicone tube set
For filling machine parts	06 x 12 mm	1000 mm	02 No	Pre & Post N ₂ purging	DPST-NNN Where : DP: Dry Power Injection ST : Silicone Tube NNN: Serial No. For example :
For Disinfectant filtration	10 x 18 mm	1500 mm	01 No	Between pressure vessel & Filter housing.	
		1500 mm	01 No	Between Filter housing & SS container	

2. Pictorial Representation of Silicon Tube Set of Machine Parts for nitrogen Pre & Post Purging:



3. Pictorial Representation of Silicon Tube Set of Disinfectant filtration:



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