



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Handling, Cleaning and Destruction of Silicon Tubes

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

To lay down a Procedure for Handling, cleaning and destruction of Silicon Tubes in Linear filing machine.

2.0 SCOPE:

This SOP is applicable for Usage, Cleaning, Storage & Destruction of Silicon Tubes used in Liquid Oral.

3.0 RESPONSIBILITY:

Operating Person-Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

IPQA In-Process Quality Assurance
Ltd. Limited
No. Number
Pvt. Private
SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 Numbering System for Silicon Tube:

6.1.1 After receipt the new Silicon Tube, Officer / Executive Production shall allocate the Silicon Tube identification number as per given below procedure:

The numbering system for Silicon Tube shall be **XST/CL/NN-YYY**.

Where,

X : Indicates section (L for liquid)
ST : Indicates for Silicon Tube
/ : Indicates Separator
CL : Indicates for Colour Code

Specified Colour	Colour Code
Caramel	RS
Yellow Oxide of Iron	YL
Sunset Yellow	SY
Titanium Dioxide	TD



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Erythrosine	ER
Brilliant Blue	BB
Ponceau-4R	PR
Transparent (Without Colour)	TR
Quinoloine Yellow	QY
Tartrazine	TT
Tartrazine + Brilliant Blue (P-Green)	PG
Carmosine	CM

/ : Indicates Separator

NN : Indicates Silicon Tube Set Serial Number which starting from 01 for each colour.

- : Indicates Separator

YYY : Indicates serialization of each Silicon Tube set Serial Number which starting from 001 for each Set.

6.1.2 Each Silicon Tube shall be given a unique identification number, once number is allotted to any Silicon Tube, the same number shall not be assigned to any other Silicon Tube.

6.1.3 Officer / Executive Production shall prepare / update a list of Silicon Tube Sets as per **Annexure – III**.

6.2 Issuance and Usage of Silicon Tube:

6.2.1 Visually check the Silicon Tube thoroughly for any damages before and after usage.

6.2.2 Check the cleanliness of Silicon Tube before start the process. If cleaned Silicon Tube is kept Idle for more than the three days then again follow the cleaning procedure before use.

6.2.3 Assemble the Silicon Tube one end with the each piston of Liquid filling machine & second end with manifold connected with reservoir (filling tank) after getting line clearance from IPQA.

6.2.4 After completion of process, clean each Silicon Tube as per cleaning procedure.

6.2.5 Officer / Executive Production shall prepare / update a list of Silicon Tube Sets as per **Annexure– III**.

6.3 Cleaning:

6.3.1 Batch to Batch Change Over/ Shift End Cleaning (A- Type Cleaning):



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- 6.3.2** After completion of batch remove the in process label and affix “to be cleaned” label.
- 6.3.3** Pass the purified water through Silicon Tubes through running filling machine nozzles to get Clear solution (washed water) no any colour traces shall be observe while washed water Keeping in beaker.
- 6.3.4** After cleaning check the Silicon Tubes visually and then dry with dried filtered compressed Air and visually check for no water residual.
- 6.3.5** Officer / Executive Production shall pack the Silicon Tube in clean poly bag and affix a label as “Cleaned”.
- 6.3.6** A type cleaning shall be valid for 24 hrs. for using the silicon tube, If not used within 24 hrs. than it should be cleaned as per B type cleaning procedure after exceeding 24 hrs.
- 6.3.7** Record the cleaning activity in equipment log:
- A-Type cleaning is to done for-
- Batch to batch changeover of same product/same colour
 - Change over to from lower strength to higher strength
 - At the end of the day
- 6.3.8** Officer / Executive Production shall send it to designated storage location/cabinet.

6.4 Product to product change over (B-Type Cleaning):

- 6.4.1** After completion of batch remove the in process label and affix “to be cleaned” label.
- 6.4.2** Pass the purified water through Silicon Tubes through running filling machine nozzles for Five minutes.
- 6.4.3** Prepare 2.0% Extran MA-02 solution with purified water in a SS vessel.
- 6.4.4** Connect the one end of Silicon tube with reservoir manifold & second end shall be connected With filling machine pistons assembly and pass the above solution through Silicon Tubes through running the machine .
- 6.4.5** Drain the Extran MA-02 solution and wash the tubing with purified water by Connecting the one end of Silicon tube with reservoir manifold & second end shall be connected with filling machine pistons assembly.
- 6.4.6** Finally pass the hot purified water through Silicon Tubes through running filling machine nozzles to get clear solution (washed water) no any colour traces shall be observe while washed water keeping in beaker.



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6.4.7 After cleaning check the Silicon Tubes visually and then dry with dried filtered compressed air and visually check for no water residual.

6.4.8 Affixed "CLEANED" STATUS label to the Silicone Tubes.

6.4.9 Record the Integrity and Cleaning Record of Silicon Tube Sets in equipment log book and maintain the cleaning record in **Annexure – II**.

B-Type cleaning is to be done for-

-Product change over

-Change over to lower strength of same product

-After 24 hours of A-Type cleaning before use.

-After maintenance of major breakdown.

-Change over to upper strength of different color.

- If the silicon tube is not use within 72 hours than clean the silicon tube before use.

-After 3 batch of same campaign.

6.5 Rejection and Destruction of Silicon Tubes:

6.5.1 Visually inspect each Silicon Tube for any damage during processing or cleaning activity.

6.5.2 If Silicon Tube is not suitable for use in production then intimate to Head Production.

6.5.3 Reject the Silicon Tube in the presence of Production, QA & Engineering personnel.

6.5.4 Cut the Silicon Tube in to small pieces by scissor/cutter, put in a polythene bag & send to scrap yard for destruction.

6.5.5 Officer / Executive Production shall replace the rejected Silicon Tube with new Silicon Tube and use it after assigning the unique identification number.

6.5.6 Replace the silicon pipe after every one year or whenever required

6.5.7 Maintain the destruction record as per **Annexure – IV**.

7.0 ANNEXURES:

ANNEXURE NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Integrity and cleaning record of silicon tube sets	
Annexure-II	List of Silicon Tube Sets	
Annexure-III	Issuance and Destruction Record of Silicon Tubes	



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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

