



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Handling of Flexible tubes/Silicon gaskets	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a Procedure for Handling of Flexible tubes / Silicon gaskets.

### 2.0 SCOPE:

This SOP is applicable for Handling of Flexible tubes/Silicon gaskets in Ointment section.

### 3.0 RESPONSIBILITY:

Officer / Executive Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

BPR	Batch Packing Record
BPCR	Batch Production and Control Record
IPQA	In-process Packing Quality Assurance
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

#### 6.1 NUMBERING SYSTEM FOR FLEXIBLE TUBES:

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

The numbering system for Flexible Tube shall be **XFT/CL/NN-YYY**.

Where,

<b>X</b>	:	Indicates section (O for Ointment)
<b>FT</b>	:	Indicates for Flexible Tube
<b>/</b>	:	Indicates Separator
<b>CL</b>	:	Indicates for Color Code
<b>/</b>	:	Indicates Separator
<b>NN</b>	:	Indicates Flexible Tube Set Serial Number which starting from 01 for each color.
<b>-</b>	:	Indicates Separator



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Handling of Flexible tubes/Silicon gaskets	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

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

Flexible Tubes	Identification No.
General	XFT/GN/NN-YYY.

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

**6.1.3** Officer / Executive Production shall prepare / update a list of Flexible Tube Sets as per **Annexure I**.

### 6.2 ISSUANCE AND USAGE OF FLEXIBLE TUBE:

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

**6.2.2** Check the cleanliness of Flexible Tube before start the process. If cleaned Flexible Tube is kept Idle for more than the 72 Hours then again follow the cleaning procedure before use.

**6.2.3** Assemble the Flexible 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 Flexible Tube as per cleaning procedure.

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

### 6.3 CLEANING:

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

**6.3.1.1** After completion of batch remove the in process label and affix “to be cleaned label.

**6.3.1.2** Pass the purified water through Flexible Tubes through running filling machine nozzles to get Clear solution (washed water) no any colour traces shall be observed while washed water keeping in beaker.

**6.3.1.3** After cleaning check the Flexible Tubes visually and then dry with dried filtered compressed Air and visually check for no water residual.

**6.3.1.4** Officer / Executive Production shall pack the Flexible Tubes in clean poly bag and affix a label as “Cleaned”.

**6.3.1.5** A Type cleaning shall be valid for 48 hrs. for using the Flexible tubes, If not used within 48 hrs. Than it should be cleaned as per B type cleaning procedure after exceeding 48 hrs.

**6.3.1.6** Record the cleaning activity in equipment log.



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Handling of Flexible tubes/Silicon gaskets	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 6.3.1.7 A-Type cleaning is to be done for

- Batch to batch changeover of same product
- Change over to from lower strength to higher strength
- At the end of the day

6.3.1.8 After cleaning Officer / Executive Production shall send it to designated storage area

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

6.3.2.1 After completion of batch remove the in process label and affix “to be cleaned” label.

6.3.2.2 Pass the purified water through Flexible Tubes through running filling machine nozzles for Five minutes.

6.3.2.3 Prepare 2.0% Extran MA-02 solution with purified water in a SS vessel.

6.3.2.4 Connect the one end of Flexible tubes with manifold (If required) & second end shall be connected with filling machine pistons assembly and pass the above solution through Flexible Tubes through running the machine.

6.3.2.5 Drain the Extran MA-02 solution and wash the tubing with purified water by connecting the one end of Flexible tubes with manifold & second end shall be connected with filling machine pistons assembly.

6.3.2.6 Finally pass the hot purified water through Flexible 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.

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

6.3.2.8 Affixed “CLEANED” status label to the Flexible Tubes.

6.3.2.9 Record the cleaning activity in equipment log.

### 6.3.2.10 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.
- If the Flexible tube is not use within 72 hours than clean the Flexible tubes before use.



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Handling of Flexible tubes/Silicon gaskets	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

- After 5 campaign batches.

### 6.4 REJECTION AND DESTRUCTION OF FLEXIBLE TUBES:

- 6.4.1 Visually inspect each Flexible Tubes for any damage during processing or cleaning activity.
- 6.4.2 If Flexible Tubes is not suitable for use in production then intimate to Head Production.
- 6.4.3 Reject the Flexible Tubes in the presence of Production, QA & Engineering personnel.
- 6.4.4 Cut the Flexible Tubes in to small pieces by scissor/cutter, put in a polythene bag & send to scrap yard for destruction.
- 6.4.5 Officer / Executive Production shall replace the rejected Tubes with new Flexible Tubes.
- 6.4.6 Replace the Flexible tubes after every one year or whenever required

### 6.5 HANDLING OF FLEXIBLE GASKETS:

- 6.5.1 Silicon gaskets should be verified before starting of the batch and after completion of the batch.
- 6.5.2 If any discrepancy is found in silicon gaskets like cracking, damage, unfit for use, it shall be removed from area immediately and replaced with new gasket.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Issuance & cleaning record of flexible tubes	
Annexure-II	List of flexible tubes set	
Annexure-III	Issuance & destruction record of flexible tubes	

**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.



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production (External Preparation)	<b>SOP No.:</b>
<b>Title:</b> Handling of Flexible tubes/Silicon gaskets	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 10.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By





