



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Cleaning and Sterilization of Goggles

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 6

### 1.0 OBJECTIVE:

To lay down the procedure for Cleaning & Sterilization of Goggles.

### 2.0 SCOPE:

This SOP is applicable to Cleaning & Sterilization of Goggles at Production Department.

### 3.0 RESPONSIBILITY:

Officer / Executive Production

### 4.0 ACCOUNTABILITY:

Head - Production

### 5.0 ABBREVIATIONS:

Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SLS	Sodium Lauryl Sulphate
SOP	Standard Operating procedure
SS	Stainless Steel
UV	Ultra Violet
WFI	Water For Injection

### 6.0 PROCEDURE:

**6.1** Issue goggle and give a unique Number to each goggle for its identification and traceability.

**6.2** Numbering shall be done with permanent marker.

**6.3** Numbering system shall be done as follows:

GOG/XX/YY-NNN

**Where,**

GOG : Goggle

XX : Section Code

YY : year of Issuance

NNN : Serial Number



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**6.4** Section Code shall be as below:

S.No.	Section	Section Code:
1	DPI	DP
2	Three Piece	TP
3	Ampoule Line	AM
4	FFS Line	FF

**6.5** Record the issuance of goggle as per **Annexure-II**.

**6.6** Collect all the used goggle from Sterile & manufacturing area in SS container. Send them to unit preparation room for cleaning.

**6.7** Clean the goggles with WFI.

**6.8** Clean the SS Container with 0.1 % SLS using Nylon Brush and flush them with Purified Water till frothing disappears.

**6.9** Wash with Purified Water till the frothing disappears and finally rinse with WFI.

**6.10** After cleaning and drying keep one goggle with each set of Garment in the Dacron bag.

**6.11** Sterilize the goggle along with the set of garment in autoclave.

**6.12** After completion of sterilization cycle unload and transfer to garment cubicle of entry Change room.

**6.13** Record the detail in “Goggle cleaning and Sterilization Record” as per **Annexure –I**.

**6.14** The goggle can be sterilized upto maximum 40 sterilization cycle, if physically found OK.

**6.15** Record the detail of sterilization cycle in the **Annexure –III**.

**6.16** If physical condition of goggle is not good, do not use and discard the goggle. Record the same in the **Annexure-III**.

**6.17** Reason for destruction either completion of permissible sterilization cycle or due to any Defect shall be mentioned in the **Annexure-III**.

**7.0 ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Cleaning and sterilization record of Goggle	
Annexure-II	Issuance Record for Goggle	
Annexure-I	Sterilization cycle record of clean area goggles	



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<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	3 of 6	

**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:

In-house

### 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 – III STERILIZATION CYCLE RECORD OF CLEAN AREA GOGGLES

**Block:**  
**Goggle I.D. No.:**

**Department/Section:**  
**Date of Issuance**

Cycle No.	1	2	3	4	5	6	7	8	9	10
Load No.										
Sign. & Date										
Cycle No.	11	12	13	14	15	16	17	18	19	20
Load No.										
Sign. & Date										
Cycle No.	21	22	23	24	25	26	27	28	29	30
Load No.										
Sign. & Date										
Cycle No.	31	32	33	34	35	36	37	38	39	40
Load No.										
Sign. & Date										

**Discarded & Destroyed on :** \_\_\_\_\_

**Reason :**

**Remarks :**

**Done By**  
**Sign & Date**

**Verified By**  
**Sign & Date**