



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Sterilization of Goggles	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable to Cleaning and Sterilization of Goggles of Production Area at

3.0 RESPONSIBILITY:

Officer/Executive – Production.

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITIONS:

Not Applicable

6.0 PROCEDURE:

- 6.1** Collect all sterile area Goggles in SS container and bring them to Washing & Sterilization room through Air Lock-V.
- 6.2** Clean the goggles with purified water.
- 6.3** Clean the SS container with 70% IPA.
- 6.4** Using Nylon Brush and flush them with Purified Water till frothing disappears.
- 6.5** Keep the goggles in SS container.
- 6.6** Sterilize the goggles at 121.4°C for 30 minutes along with other accessories.
- 6.7** Open the door from sterile area and unload the goggles under Laminar Air Flow unit in cooling zone. Then transfer them in sterile garment cabinet.
- 6.8** Record the cleaning and sterilization details of goggles in **Annexure-I**
- 6.9** Record the details of goggles sterilization Cycles as per **Annexure-II**
- 6.10** Sterilization cycles of goggles should not be more than 50. The goggles shall be discarded after 50 sterilization cycles or in case of physical damages in presence of IPQA person.



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6.11 Frequency: Daily

7.0 ABBREVIATION:

SOP	Standard Operating Procedure
WFI	Water for Injection
Ltd.	Limited
No.	Number
QA	Quality Assurance
IPA	Iso-propyl-alcohol
UV	Ultraviolet Light

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No
Annexure-I	Cleaning & Sterilization Record of Goggles	
Annexure-II	Sterilization Cycles Record Of Goggles	

9.0 DISTRIBUTION:

- Controlled Copy No.1 Production Department
- Master Copy Quality Assurance Department

10.0 REFERENCE:

In-House

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 DEVILS

PRODUCTION DEPARTMENT

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ANNEXURE-II

	STERILIZATION CYCLES RECORD OF GOGGLES
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Department:
Goggles I.D. No.:

Line:
Date of Issuance:

Date										
Cycle	1	2	3	4	5	6	7	8	9	10
Done By Sign & Date										
Date										
Cycle	11	12	13	14	15	16	17	18	19	20
Done By Sign & Date										
Date										
Cycle	21	22	23	24	25	26	27	28	29	30
Done By Sign & Date										
Date										
Cycle	31	32	33	34	35	36	37	38	39	40
Done By Sign & Date										
Date										
Cycle	41	42	43	44	45	46	47	48	49	50
Done By Sign & Date										

Discarded & Destroyed on: _____

Reason: _____

Sign/Date (Production)

Sign/Date (QA)