STANDARD OPERATING PROCEDURE

Title: Cleaning and Sterilization of Filters

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 5	

1.0 OBJECTIVE:

To lay down a procedure for cleaning and sterilization of filters.

2.0 SCOPE:

This SOP is applicable for cleaning and sterilization of filters used in Production Department.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

%	Percent
IPA	Isopropyl Alcohol
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 PRECAUTIONS:

6.1.1 Handle the Filter carefully to avoid any possible damage / extraneous contamination.

6.1.2 Never remove the filters from line when it is in under operation.

6.1.3 Filter should be clean with their respective cleaning agent.

6.1.4 When observed any physical damage, filter should be replaced by newer one and discard the damaged filter.

6.2 CLEANING AND STERILIZATION OF CARTRIDGE FILTERS:

6.2.1 Dismantle the filter from their housing and transfer it in the unit preparation area.

6.2.2 Clean the filter housing with WFI.

6.2.3 Take out the Filter & Dip into 70% IPA solution for 20 minutes.

6.2.4 Clean the filter with WFI by flushing of WFI in case of hydrophilic Cartridge only.

6.2.5 Dry the filter by flushing of Compressed Air.

6.2.6 Re-assembled the cleaned filter in their respective housing, if Cartridge filter used in Aseptic
Area or Direct Contact in Product, filter should be sterilized before installation.

6.2.7 Perform the Sterilization process of the Cartridge filters as per respective SOP.

6.3 CLEANING AND STERILIZATION OF AUTOCLAVE AIR VENT FILTER:

6.3.1 Remove the filter from autoclave chamber vent port and transfer to Unit Preparation area for cleaning and attached another sterilized filter on the same position.

6.3.2 For cleaning of vent filter, dip the filter in 70% IPA for 20 minute.

6.3.3 After that dry it by flushing of compressed Air.

6.3.4 Check physical condition of the filter visually, if it is physically damaged then discard it.

6.3.5 Perform the Sterilization process of the vent filters as per respective SOP.

6.4 CLEANING AND STERILIZATION OF CAPSULE FILTERS:

6.4.1 Remove the filter from their line and transfer it in Filter Cleaning Area.

6.4.2 For cleaning of Capsule filter, dip the filter in 70% IPA for 20 minute.

6.4.3 In case of hydrophilic Capsule clean the filter by flushing of WFI.

6.4.4 After that dry it by flushing of compressed Air.

6.4.5 Check physical condition of the filter visually, if it is physically damaged then discard it.

6.4.6 Perform the Sterilization process of the vent filters as per respective SOP.

6.5 Record the filter cleaning, sterilization and sterilization cycle details of other than product filter in **Annexure-I**, "**Filter Cleaning and Sterilization Record".**

Note: Cartridge filter and Capsule Filter should be replaced by newer one when it is failure in BPT/WIT/ FFT or after completion of recommended Sterilization Cycle.

6.6 FREQUENCY:

6.6.1 **Hydrophilic Filter** – After Operation/Wherever required.

6.6.2 Hydrophobic Filter –15± 4 days/Wherever required.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Filter Cleaning and Sterilization Record	
Annexure-II	Integrity Test Value of the Filters	

ENCLOSERS: 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

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ANNEXURE – I
FILTER CLEANING AND STERILIZATION RECORD

Make:- **Filter Lot No.:** **Serial No.**

Filter Size:- **Pore size of Filter:** **Location:**

Date	Type of Filter	Cleaning Time		Done By	Sterilization Time		Cumulative Sterilization Cycle No.	Destroyed By (if sterilization cycle completed)	Checked By Production	Verified By QA
		From	To		From	To				

Remark:

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ANNEXURE – II
INTEGRITY TEST VALUE OF THE FILTERS

Category	Filter size	Pore size	Manufacturer	Catalogue No.	Test to be performed		MOC	Max. sterilization cycle
					Test pressure	Test value		
Hydrophilic	10 inch	0.45µ+ 0.2 µ	Sartorius		3200 mbar	Bubble point should not found below test value	PES	25
	30 inch	0.45µ+ 0.2 µ	Sartorius		3200 mbar		PES	25
	10 inch	0.2 µ	Pall		2760 mbar		PVDF	25
	10 inch	0.2 µ	Millipore		3100 mbar		PVDF	25
	30 inch	0.2	Millipore		3100 mbar		PVDF	25
	10 inch	0.2 µ	MDI		3440 mbar		PES	15
Hydrophobic	5 inch	0.2 µ	MDI		1520 mbar	Bubble point should not found below test value	PTFE	80
	10 inch	0.2 µ	Pall		1100 mbar		PTFE	80
	5 inch	0.2 µ	Pall		1380 mbar		PTFE	80
	10 inch	0.2 µ	Pall		1380 mbar		PTFE	80
	5 inch	0.2 µ	Millipore		1100 mbar		PTFE	80
	10 inch	0.2 µ	Millipore		1100 mbar		PTFE	80
Hydrophobic	5 inch	0.2 µ	Sartorius		700 mbar		PTFE	80