



STANDARD OPERATING PROCEDURE

Title: Replacement of Hydrophobic Cartridge Filter at Different Locations

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

To lay down the procedure for replacement of hydrophobic cartridge filter at different locations.

2.0 SCOPE:

This SOP is applicable for replacement of hydrophobic cartridge filter at different locations.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BFS	Blow-Fill & Seal
BPT	Bubble Point Test
FFT	Forward Flow Test
IPA	Iso Propyl Alcohol
Ltd.	Limited
M/C	Machine
NA	Not Applicable
No.	Number
Pvt.	Private
QA	Quality Assurance
SHWSS	Super-Heated Water Spray Sterilizer
SIP	Sterilization in Place
SOP	Standard Operating Procedure
WFI	Water for injection
WIT	Water Intrusion Test

6.0 PROCEDURE:

6.1 ENSURE THE AVAILABILITY OF THE FOLLOWING:

- Palltronic m/c
- Hydrophobic Cartridge Filter
- Cartridge Filter Housing
- Water for injection
- 0.22 μ filtered Compressed Air (6 Kg/cm²)
- Power Supply (220V)

6.2 PROCEDURE OF CHANGING OF HYDROPHOBIC CARTRIDGE FILTERS:

6.2.1 For BFS m/c (Blowing air, Support air, Buffer air):



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6.2.2 Check the cartridge filter integrity test (WIT, BPT & FFT) as per SOP of hydrophobic cartridge filter, if it fails, take new filters and check integrity test and sterilize then install in their respective housing.

6.2.3 Maximum 80 SIP cycles permissible.

6.2.4 The smooth working of the m/c requires appropriate flow rate of filtered air, filter can be replace if physical condition is not proper (color change) while integrity of filter found ok.

6.2.5 For Autoclaves (Garment/SHWSS):

6.2.6 Check the cartridge filter integrity test as per SOP of hydrophobic cartridge filter, if it fails, take new filters and check integrity test, then sterilized and install in their respective housing.

6.2.7 Maximum 80 SIP cycles permissible.

6.2.8 For mixing, Holding tank air vent, Air- line, Nitrogen line, disinfectant air line:

6.2.9 Check the cartridge filter integrity test of hydrophobic cartridge filter, if it fails, take new filters and check integrity test, sterilized and install in their respective housing.

6.2.10 Maximum 80 SIP cycles permissible.

6.3 PRECAUTIONS:

6.3.1 During handling of cartridge filter, take precaution to avoid any damage / contamination of the cartridge filter / air- line.

6.3.2 Frequency:

6.3.2.1 Whenever the WIT / BPT/recommended test fails.

6.3.2.2 Whenever cartridge filters get choked/ prohibiting smooth running of operation.

6.3.2.3 Whenever SIP cycles are over.

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No.1 Quality Assurance
- Controlled Copy No.2 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable



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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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