STANDARD OPERATING PROCEDURE				
Title: Procedure for Filtration of Bulk Solution and Changing of product Transfer Pump				
SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 6	

1.0 OBJECTIVE:

To lay down a Procedure for Filtration of Bulk Solution and Changing of product Transfer Pump.

2.0 SCOPE:

This SOP is applicable for Filtration of Bulk Solution and Changing of Product Transfer Pump in Production Area.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBRIVATION:

CIP	Clean In Place
IPA	Iso Propyl Alcohol
NA	Not Applicable
No.	Number
QA	Quality Assurance
QC	Quality Control
SIP	Sterilization In Place
SOP	Standard Operating procedure
WFI	Water For Injection
GM	General Manager
BMR	Batch Manufacturing Record
PVT.	Private
Ltd.	Limited

6.0 PROCEDURE:

6.1 FILTRATION OF BULK SOLUTION:

6.1.1 Manufacturing to Holding tank:

6.1.1.1 Clean the Cartridge Filter Housing containing 1.2µ, 0.6 µ and 0.22µ Cartridge Filters respectively.

6.1.1.2 Assemble the Cartridge Filter and housing and check for proper fixing of "O – Ring" to ensure complete tightness of the Filtration assembly.

6.1.1.3 Perform Bubble Point Test of Cartridge Filter (0.22µ) to ensure its integrity before Sterilization.

6.1.1.4 Perform Sterilization of assembled Cartridge filter housing containing Cartridge Filter of 1.2µ, 0.6 µ and 0.22 µ.

6.1.1.5 Release the air from filter prior to startup of the filtration operation.

6.1.1.6 Start the Batch Filtration after release of the Batch from the QC and as per instructions and presence of Manufacturing Chemist.

6.1.1.7 After completion of filtration, perform the Bubble Point Test of the Cartridge Filter (0.22µ) to confirm its Post Filtration Integrity.

6.1.1.8 Record the Filtration related details (Time, pressure) in respective BMR.

6.1.2 Holding tank to BFS machine:

6.1.2.1 Clean the Cartridge Filter Housing containing 0.2µ and 0.2µ on BFS machine Cartridge Filters respectively.

6.1.2.2 Assemble the Cartridge Filter and housing and check for proper fixing of "O – Ring" to ensure complete tightness of the Filtration assembly.

6.1.2.3 Perform Bubble Point Test of Cartridge Filter to ensure its integrity before Sterilization.

6.1.2.4 Perform Sterilization of assembled Cartridge filter housing containing Cartridge Filter of 0.2µ and 0.2µ on BFS machine

6.1.2.5 Release the air from filter prior to startup of the filling operation.

6.1.2.6 Start the Batch filling after required solution transferred to holding tank.

6.1.2.7 After completion of filling, perform the Bubble Point Test of the Cartridge Filter to confirm the Post filling Integrity.

6.1.2.8 Record the filtration and filling related details at specified place in respective BMR.

6.2 CHANGING OF PRODUCT TRANSFER PUMP DURING RUNNING OF PRODUCTION:

6.2.1 Switch OFF the electric supplies of the pump.

6.2.2 Close the main bottom outlet valve of the tank and upper side valve of the pump.

6.2.3 Intimate to engineering department with breakdown intimation slip.

6.2.4 Remove the outer cover from the pump.

6.2.5 Electrician shall check that, what the problem is exactly.

6.2.6 If the problem is associated with the electric supply and not with the system, the same shall be rectified in place.

6.2.7 If the problem is associated with motor or pump seal, clean and sanitized the pump then pump should be replaced through pass box, which is in working condition (Stand By).

6.2.8 Before start the process, perform CIP of product pump and send the wash water sample to QC for analysis. Now perform the SIP of the pump.

6.2.9 Record the product pump transfer detail in **Annexure-I.**

6.3 PRODUCT PUMP CHANGE FROM MANUFACTURING TO HOLDING TANK:

6.3.1 In Case Manufacturing Tank is Empty:

6.3.1.1 Incase product pump failure during product transfer from mfg. to holding, then stop the filtration process immediately.

6.3.1.2 Then clean the External surface of stand by pump using IPA 70%, and perform the CIP of the product pump with holding tank, after the CIP process, send the sample to QC for pH & conductivity.

6.3.2 In Case Manufacturing Tank is filled with Solution:

6.3.2.1 Then clean the stand by pump using IPA 70%, and perform the offline CIP of the product pump with running WFI in manufacturing area and after CIP send the sample to QC for pH & conductivity.

6.3.2.2 Perform the offline SIP (steaming) of the product pump in manufacturing area.

6.3.2.3 After getting CIP sample result from QC, Now connect the product pump with product line and start the filtration process.

6.4 PRODUCT PUMP CHANGE FROM (HOLDING TANK TO BFS MACHINE):

6.4.1 In Case Holding Tank is Empty:

6.4.1.1 Then clean the External surface of stand by pump using IPA 70%, and perform the CIP of the product pump with holding tank, after the CIP process, send the sample to QC for pH & conductivity.

6.4.1.2 Perform the SIP of the product pump along with holding tank in Filtration area (holding).

6.4.1.3 After getting CIP sample result from QC, connect the product pump with product line and start the filtration process (holding to BFS m/c).

6.4.2 In Case Holding Tank is Filled with Solution:

6.4.2.1 Then clean the External surface of stand by pump using IPA 70%, and perform offline CIP in holding area & send the sample for pH conductivity BET if applicable.

6.4.2.2 Now Perform the SIP (steaming) of the product pump by excluding holding vessel along with product line in Filtration area (holding area).

6.4.2.3 After getting CIP sample result from QC, start the filtration process (Holding to BFS m/c).

6.5 PRECAUTIONS:

6.5.1 Electric supply should be OFF before dismantling the WFI circulation pump.

6.5.2 Do not touch the product transfer pump SS line when it is under run.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Replacement Of Product Transfer Pump	
Annexure-II	Bulk Solution Filtration Record	

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.

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
REPLACEMENT OF PRODUCT TRANSFER PUMP

S.No.	Location & Detail	Offline CIP Time	Offline SIP Time	Checked by	Verified by	Remarks

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ANNEXURE – II
BULK SOLUTION FILTRATION RECORD

Block		**Section**		**Line**	
Location		**Filter housing ID No.**			

Installed					Operation Details				Discarded			Remarks
Date	**Filter No.**	**Make**	**Lot No.**	**Pore Size**	**Product Name**	**Batch No.**	**Nos. of Sterilization Cycle (Cumulative)**	**Qty. of Sol. Filtered (Cumulative)**	**Date**	**Time**	**By Sign & Date**	