STANDARD OPERATING PROCEDURE

Title: Filtration of Bulk Solution

SOP No.:		**Department:**	Production	
		Effective Date:		
Revision No.:	00	**Revision Date:**		
Supersede Revision No.:	Nil	**Page No.:**	1 of 3	

1.0 OBJECTIVE:

To lay down a Procedure for Filtration of Bulk Solution.

2.0 SCOPE:

This SOP is applicable for Filtration of Bulk Solution in Production Area.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

Ltd.	Limited
SOP	Standard Operating Procedure
No.	Number
QA	Quality Assurance
GM	General Manager
BMR	Batch Manufacturing Record
PVT.	Private

6.0 PROCEDURE:

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

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

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

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

6.5 Release the air from filter prior to start up of the filtration operation.

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

6.7 After completion of filtration, perform the Bubble Point Test of the Cartridge Filter to confirm the Post Filtration Integrity.

6.8 Record the Filtration related details at specified place in respective BMR.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Bulk Solution Filtration Record	

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.

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
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**	