User Requirement Specifications
Depth Filtration

Block Code	Area	Identification #	Quantity	Capacity
B1	Hep B	B1-DFT 01	1	10 to 180 LPH

Table of Contents

1.0 APPROVAL SIGNATURE 4

2.0 EQUIPMENT DESCRIPTION 5

3.0 PROCESS DESCRIPTION 7

3.1 INPUT & CHARGING METHOD 7
3.2 BRIEF PROCESS STEPS 7
3.3 OUTPUT & DISCHARGING METHOD 8

4.0 PRODUCTIVITY REQUIREMENT 8

4.1 DESIRED/ SUGGESTED CAPACITY 8
4.2 STANDARD BATCH SIZE 8
4.3 CHANGE OVER TIME 8
4.4 OTHER PRODUCTIVITY REQUIREMENT 8

5.0 CONTAINMENT 8

6.0 GMP REQUIREMENTS 8

6.1 PROCESS CONTROL 8
6.2 FAILURE MODE DETECTION 9
6.3 IN –PROCESS CONTROL 9
6.4 LEVEL OF INSTRUMENTATION 9
6.5 BATCH DATA DISPLAY AND RECORD PRINTING 9
6.6 GMP REQUIREMENTS (OTHERS) 9
6.7 SPECIFIC REQUIREMENTS 9
6.8 SPARES AND CONSUMABLES 10

7.0 CONSTRAINTS 10

7.1 EQUIPMENT LOCATION AND AVAILABLE SPACE 10
7.2 AVAILABLE UTILITY 10

8.0 ABBREVIATION 11

9.0 REVISION INDEX 11

URS Annexure List:

URS Annex No.	Detail
1	Layout showing location of the installation of the Depth Filtration for Multi Bacterial Bulk block for Hep-B

1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective should be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

NNE Pharmaplan India Limited			
Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Engineer – Process	for. Meghe	13-04-2016
Checked by			
Mr. Yogesha M J	Process Engineer	Yogesha-MJ	13-04-2016
Approved by			
Dr. Harshad Mali	Lead Process Engineer	[illegible]	13-04-2016

HLL Biotech Limited			
Name	Designation	Signature	Date
Reviewed by			
User Department (MBB Block – Rep B) CH. RAJESH	Assistant Manager	[illegible]	16-04-2016
Project / Engineering Department A. ANTO FELIX	Manager	[illegible]	16-04-2016
QA Dept Kayakhandan	Sr. Manager, QA	[illegible]	16-04-16
Approved By			
Head of User Department (MBB Block – Rep B) Dr. SUBRAMANIAM V. MANTHA	Head-UD	M.V. Subramaniam	16-04-2016
Head of User Department (QA) [illegible]	DGM	[illegible]	16-04-2016
Authorized by			
Project Authority RAMAN K. R.	CEO	[illegible]	18.4.16

2.0 EQUIPMENT DESCRIPTION

The **Depth Filtration skid** shall consist of following parts in order to operate as required by the user

Sl. No.	Parts	Hep B
1.	cGMP compliance	Required
2.	Type	Forward flow Depth Filtration
3.	Flow rate	10 LPH to 180 LPH
4.	Operational temperature	-10˚C to 150°C
5.	Operating pressure	-1 to 8 bar(g)
6.	MOC of the housing	AISI 316L stainless
7.	MOC of the Filter media	Vendor to specify
8.	Size of the Filter media	Vendor to specify
9.	No of disks to accommodate	3x3dom pad system
10.	Number of Inlets ports required	1
11.	Number of outlet ports required	1
12.	Vent port	1 x 3 for each dom 1 vent port should be provided
13.	Surface finish	< 0.5µ Ra for filling line and < 0.8µ Ra for lyophilizer) and external surface matte finish (< 1.2µ Ra)
14.	Provision for CIP and SIP of the housing	Required
15.	Valves	To control the flow rate of the process liquids in feeding lines
16.	System supported for complete auto CIP & SIP procedures	Required
17.	Skid should have support stand with lockable wheels	Required
18.	Accessories	The package should include and supply all required accessories such as (not limited to)connectors, tubings, seals, O-rings, flanges, bolts, nuts, clamps, Allen screws and keys, springs, gaskets and washers required for the skid.

Note: All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.1 to 4.1.10, 4.1.12 to 4.1.22, 4.2, 5.5, 5.6, 5.7, 5.8, 5.9.3, 5.9.4, 5.9.5
- FDA Guidance for industry- Documentation for sterilization Process Validation

Note:

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. In case of any deviation, a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	Special Instruction a. If no comments against any specification shall be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non-compliant and rejected.
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01
XII.	Refer Tender document with URS; NPI_120310_EQP_S1_TD_17

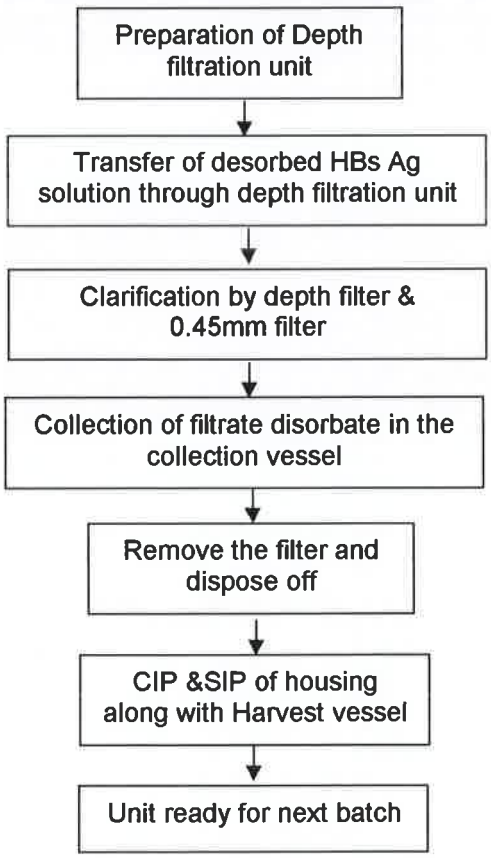
Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 The desorbed HBs Ag solution is collected in vessel	
3.1.2 The product is fed to the depth filter to remove cell debris.	
3.2 Brief Process Steps	

Assembly: The depth filters are installed in stack and connections are prepared to the Harvest and Collection Vessels.

Filtration: The product is transferred continuously through depth filter.

Disassembly: The filters and the connections are dismantled and filters are disposed of.

The Main sequence of the system is given below:



The Depth filtration skid should be designed to control the following steps	
3.2.1 The equipment will be designed to achieve a maximum recovery of the final product	
3.2.2 Product losses must be minimized	
3.2.3 Process parameters like flow and pressure will be controlled using manual valves	
3.2.4 All transfers and connections to the depth filter will be implemented using closed system approach.	
3.3 Output & Discharging method	
3.3.1 Transfer of the clarified product to the respective collection vessel for next process	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
4.1.1 The equipment should be suitable to operate at the flow rate of 10 to 180 litres per hour	
4.1.2 Infeed Volume will be approx. 400L per each sub lot	
4.1.3 Equipment shall be designed for minimum hold up volumes.	
4.1.4 Maximum batch cycle time will be 6 hours.	
4.1.5 All product contact surfaces will be SS316 L.	
4.1.6 Should have provision for CIP of all equipment and piping in product contact.	
4.1.7 Filter size: 2µ	
4.2 Standard batch size	
Not Applicable	
4.3 Change Over Time	
Not Applicable	
4.4 Other Productivity Requirement	
Not Applicable	
5.0 CONTAINMENT	
Not Applicable	
6.0 GMP REQUIREMENTS	
6.1 Process control	
System will be controlled using manual valves.	

6.2 Failure mode detection

Not Applicable

6.3 In –Process control

System will be controlled using manual valves.

6.4 Level of instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Instrumentation	Equipment Operating Range (Min – Max)
Pressure	Diaphragm Pressure gauge for filter	Pressure gauge	-1 to 8 bar(g)
Temperature	Temperature sensor in drain line for SIP	Temperature sensor	-10 to 150 °C
Conductivity	To measure the conductivity at the outlet	Conductivity sensor	TBD
pH	To measure the pH at the outlet	pH sensor	0 - 14

6.5 Batch data display and record printing

Manual batch reports to be maintained.

6.6 GMP requirements (Others)

6.6.1 Vendor to give code numbers for each component

6.6.2 All ports/valves/filters and tubing connections shall be sanitary type, in compliance to ASME BPE.

6.6.3 Biocompatibility tested in accordance with USP<87> Class VI and USP <88> Class VI

6.6.4 ISPE Baseline Guide,Volume 6-bipharmaceuticals

6.6.5 All the tubings for CIP, WFI and waste shall be sanitary type, in compliance to ASME BPE.

6.6.6 Internal and external finish shall be electro polished to < 10 Ra

6.7 Specific requirements

6.7.1 The depth filtration skid must have wheels for mobility and it must be possible to lock the wheels.

6.7.2 All parts (valves, transmitters, etc) should be easy to access and removable to facilitate routine maintenance.

6.7.3 Diaphragm pressure guage shall be provided for the filter housing to monitor the filtration pressure	
6.7.4 Temperature sensor shall be provided in the drain line to monitor the sterilisation temperature.	
6.7.5 It must be possible to replace and install different numbers of filter cartridges.	
6.7.6 All points of use, mechanical, instrument, control and electrical items or components (including cables) must be identified by a secure, legible, permanently marked, conditions resistant label or tag.	
6.7.7 It must be possible to clean and sterilize the filter housing.	
6.7.8 Alarm should be provided for Flow, Temperature and Pressure if it deviates beyond the set point and tolerance limit	
CIP	
6.7.9 It must be possible to clean the equipment and piping in product or media contact	
6.7.10 Suitable accessory to be provided to spray the CIP solution within the filter housing.	
6.7.11 It must be possible to drain equipment automatically within 5min	
SIP	
6.7.12 It must be possible to sterilise equipment and piping in product or media contact by using pure steam.	
6.8 Spares and consumables	
6.8.1 Essential Spares for continuous 1 year of operation after warranty period should be provided.	
6.8.2 Essential consumables/kits for continuous 2 years of operation should be provided.	
7.0 CONSTRAINTS	
7.1 Equipment location and available space	
This equipment will be installed in the Purification and Chromatography Room of Hep B, IVC Chengalpattu **Equipment Location:** Room number: B1G040 Floor: Ground Floor Plant: Hep B Room Area: 21.53 m2 False ceiling height: 3.0 m Room temperature: 22±2 °C Relative Humidity: Not more than 55 %	
7.2 Available Utility	
a) Compressed air 6-8 bar (Report Requirement) b) WFI @ 80 deg.C	

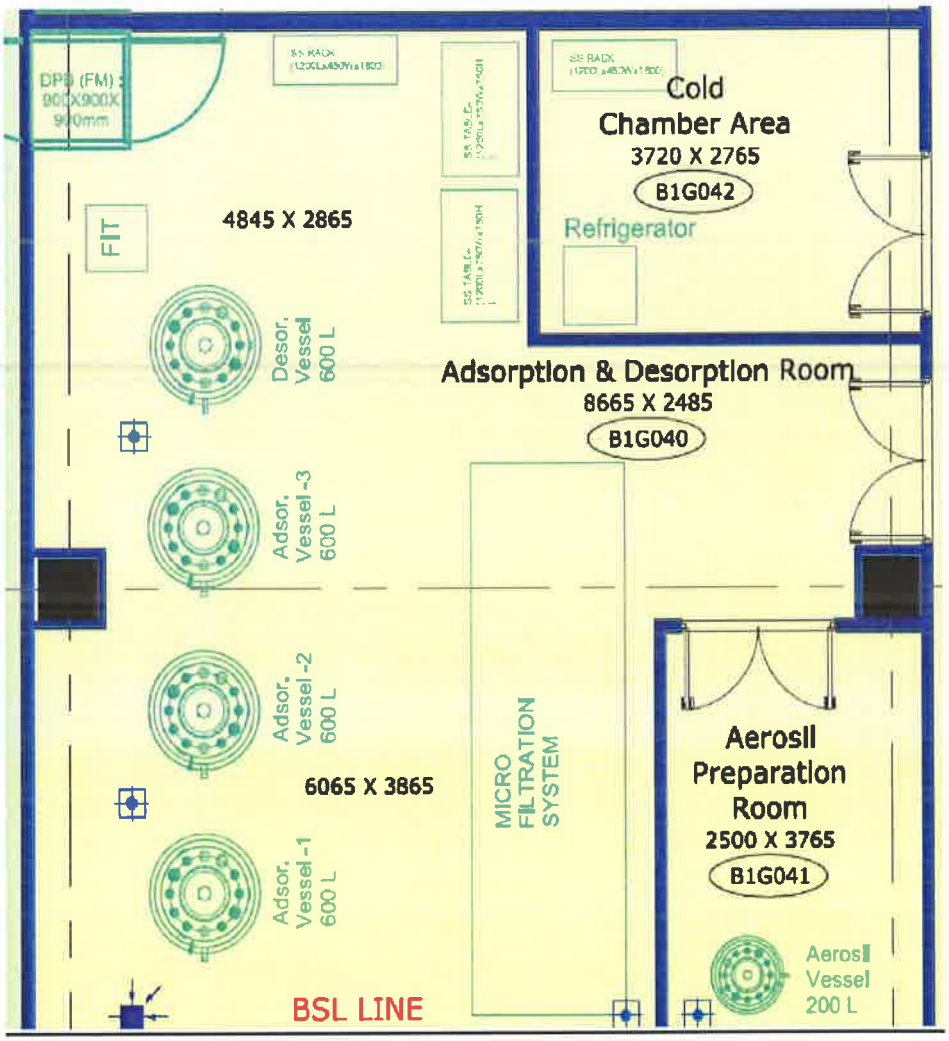
8.0 ABBREVIATION

Abbreviation	Definition
ASME	American Society of Mechanical Engineers
BPE	Bioprocessing equipment
CIP	Clean in place
DFT	Depth Filter
DQ	Design Qualification
LPH	Liter per hour
MOC	Material Of Construction
NA	Not applicable
QA	Quality Assurance
SS	Stainless steel

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	18-12-2015	First Draft for Client's Review
01	05-04-2016	Updated as per comments given by HBL dated 17-02-2016 by mail

URS Annexure 1: LAYOUT POSITION

Room No: B1G040:

Depth Filtration Area