

# HLL BIOTECH LIMITED, CHENNAI

## INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

### User Requirement Specifications

Equipment/System	Sterile Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 01
Effective Date	17.7.2014	Revision#	02



## User Requirement Specifications Sterile Filtration Housing Unit

Block Code	Area	Identification #	Description	Quantity
F1	Viral Vaccine Formulation- Rabies	F1-SFU 01_02&03	2 x 10"; SS filter housing train to suit Code 7 type filter cartridge	2
			1 x 10"; SS filter housing to suit Code 7 type filter cartridge	1
F1	Viral Vaccine Formulation- Measles	F1-SFU 04_05&06	2 x 10"; SS filter housing train to suit Code 7 type filter cartridge	1
			1 x 10"; SS filter housing to suit Code 7 type filter cartridge	2
F2	Bacterial Vaccine Formulation	F2-SFU 01_02&03	1 x 10"; SS filter housing to suit Code 7 type filter cartridge	3
B4	Rabies Bulk	B4-SFU 01	2 x 10"; SS filter housing train to suit Code 7 type filter cartridge	2
Q1	Quality Control	Q1-SFU 01_02&03	1 x 10"; SS filter housing to suit Code 7 type filter cartridge	3

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nne pharmaplan	<b>User Requirement Specifications</b>				 <small>HLL BIOTECH LIMITED S. Arundhan / M. Aravindhan A Government of India Enterprise</small>
	<b>Equipment/System</b>	Sterile Filtration Housing Unit			
	<b>Identification #</b>	-	<b>Document No.</b>	URS/SFU 01	
	<b>Effective Date</b>	17.7.2014	<b>Revision#</b>	02	

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HLL BIOTECH LIMITED 3, Chembayal Street, Chengalpattu Tamil Nadu 603 002, India	<b>User Requirement Specifications</b>			
	Equipment/System	Sterile Filtration Housing Unit		
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### URS Annexure List:

URS Annex No.	Detail
1	List of Preferred Make of components

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nne pharmaplan	<b>User Requirement Specifications</b>			HLL BIOTECH LIMITED 3, Madhav Nagar, Chengalpattu Tamil Nadu - 603 002	
	Equipment/System	Sterile Filtration Housing Unit			
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### 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.

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# HLL BIOTECH LIMITED, CHENNAI

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### 2.0 EQUIPMENT DESCRIPTION

The equipment described in this URS is a portable type with skid support for Double housing and Single housing for carrying out filtration of various processes.

The unit will be used in a clean room under aseptic conditions and therefore has to comply with all requirements of cGMP.

DESCRIPTION	Remarks
<p><b>2.1 SCOPE OF SUPPLY</b> The skid mounted SS filtration train should be accommodated with 2 nos of SS Filter Housing Bell to suit 10 Inch, Code 7 filter cartridges and 1 no. of SS Filter Housing Bell to suit 10 Inch, Code 7 filter cartridge.</p>	
<p><b>A. Major components required with the system are mentioned below:</b></p> <ul style="list-style-type: none"> <li>• Filter housing and Filter Cartridges for sterile filtration, all product contact parts should be made of SS 316L and Surface finishing of the filter Inner surface – Ra &lt;0.5 Ra[EP], external surface &lt; 1.2 Ra.</li> <li>• Suitable provision to be provided for filter integrity testing.</li> <li>• The entire SS filtration housing should be sterilizable in autoclave at 121 °C</li> <li>• Diaphragm pressure gauge should be provided with TC ends above the SS housing bell and suitable end caps.</li> <li>• Inlet &amp; Outlet ports should be provided with sterilizable diaphragm valves and sanitary hose barb adapter (SS 316L) with TC clamps to suit 6 mm to 12 mm ID silicon tube.</li> <li>• ¾" SS 316L grade sanitary diaphragm vent valve should be provided in the SS housing system for venting operation.</li> <li>• Maximum design pressure of filter housing must be of 10 bar.</li> <li>• Manual diaphragm valves of sanitary type at the feed inlet and filtrate outlet to be provided.</li> </ul>	
<p><b>B. Cleaning:</b> Cleaning of the system should be done manually.</p>	
<p><b>C. Sterilization:</b> Sterilization of the system should be done in autoclave.</p>	

**D. The filtration unit should contain the followings for a smooth running of the equipment.**

S. No.	Description	Purpose	Remarks
1	Product Inlet with TC end	For attaching to the pipe line to the hose barb adaptor.	
2	Product outlet with TC end	For attaching to silicon tube to transfer to containers.	
3	Filter housing	SS316L filter housings to suit code 7 type filter cartridge.	
4	Drain valve	For draining the product remained in the filter housing at the end of the process	
5	Integrity connector	For testing the integrity of the filter	

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HBL HLL BIOTECH LIMITED S. Arundhanayagam, Director A. Govindaraj, Manager	<b>User Requirement Specifications</b>			
	<b>Equipment/System</b>	Sterile Filtration Housing Unit		
	<b>Identification #</b>	-	<b>Document No.</b>	URS/SFU 01
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**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 an 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.	<p>Special Instruction</p> <p>a. If no comments against any specification should be considered as "NO" and</p> <p>b. If there is no reply / comments against the complete URS by the vendor then it should be treated as unresponsive / technically non-compliant and rejected.</p>
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_TD_06

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Specifications	Remarks
<b>3.0 PROCESS DESCRIPTION</b>	
<b>3.1 Input &amp; Charging method</b>	
3.1.1 <b>Product inlet:</b> Solution/Component is transferred from vessel to sterile filter unit.	
<b>3.2 Brief Process Steps</b>	
3.2.1 The equipment will be used for clarification and sterile filtration of the process solutions.	
<b>3.3 Output &amp; Discharging method</b>	
3.3.1 The Filtrate will be collected into containers under BSC / LAFU for further process	
<b>4.0 PRODUCTIVITY REQUIREMENT</b>	
<b>4.1 Desired/ suggested capacity</b>	
4.1.1 Low hold – up volume.	
4.1.2 The process piping inner diameter - vendor to specify.	
4.1.3 SFU should be completely drainable.	
4.1.4 SS Housing should be compatible with code 7 type filters .	
<b>4.2 Standard batch size</b>	
Not Applicable	
<b>4.3 Change Over Time</b>	
Not Applicable	
<b>4.4 Other Productivity Requirement</b>	
Not Applicable	
<b>5.0 CONTAINMENT</b>	
Not Applicable	
<b>6.0 GMP REQUIREMENTS</b>	
<b>6.1 Failure mode detection</b>	
Not Applicable	
<b>6.2 In –Process control</b>	
Vent valve should be provided .	
<b>6.3 Level of instrumentation</b>	
Not Applicable	

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### 6.4 Batch data display and record printing

Not Applicable

### 6.5 GMP requirements (Others)

6.5.1 The housing bell should be seamless pipe with smooth polished finish.

6.5.2 Equipment parts should be easily dismantle-able and cleanable.

6.5.3 "O" rings, Gaskets (Viton/silicon/EPDM) should be of food grade.

### 6.6 Specific requirements

6.6.1 Overall size of the filtration housing train (including all the vents and supporting frame) should be compatible/suitable for sterilization/decontamination in the smallest autoclave with the height of 750mm.

6.6.2 The SS filtration system should be completely drainable.

6.6.3 Filtration Unit grid (supporting frame) should have blunt edges and should have compact handles to aid in lifting and transportation.

### 6.7 Spares and consumables

6.7.1 Vendor should provide spares for all gaskets, O-rings, TC clamps, TC blinds used in the SS filtration housing for minimum of 2 years.

## 7.0 CONSTRAINTS

### 7.1 Equipment location and available space

Not Applicable

### 7.2 Available Utility

Not Applicable

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### 8.0 ABBREVIATION

Abbreviation	Definition
ASME	American standard for manufacturing equipment
cGMP	Current Good Manufacturing Practice
HBL	HLL Biotech Limited
MOC	Material Of Construction
NNE	Novo Nordisk Engineering
NPI	NNE Pharmaplan India Ltd
NMT	Not more than
NWP	Nominal Water Permeability
TC	Tri-Clamp

### 9.0 REVISION INDEX

Revision	Date	Reason for revision
00	05-05-2014	First Draft for Client's Review
01	17-05-2014	Revised as per client comments received on 17-05-2014 on E-mail
02	04-07-2014	Updated as per MoM dated 04-07-2014

#### Annexure I. List of Preferred Make of components

S.No.	DESCRIPTION	MAKE
1	Pressure gauges	WIKA/Denver/Negele
2	Filter housing	Sartorius/ PALL/Millipore
3	Diaphragm valve(Manual)	GEMU

