

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharma plan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00



User Requirement Specifications SS Filtration Housing Unit

Block Code	Area	Identification #	Description	Quantity
R1	Measles and Rubella Bulk block	R1-SFU 01-04	1 x 10"; SS filter housing to suit Code 7 type filter cartridge	4
		R1-SFU 05-14	1 x 6"; SS filter housing to suit Code 7 type filter cartridge	10

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

HLL Pharmaplan	User Requirement Specifications			 HLL BIOTECH LIMITED <small>Company of HLL, Mysore. In a tie-up with Government of Karnataka</small>	
	Equipment/System	SS Filtration Housing Unit			
	Identification #	-	Document No.		URS/SFU 02
	Effective Date	18-04-2016	Revision#		00

Table of Contents

1.0	APPROVAL SIGNATURE	4
2.0	EQUIPMENT DESCRIPTION	5
	DESCRIPTION.....	5
3.0	PROCESS DESCRIPTION	7
3.1	INPUT & CHARGING METHOD	7
3.2	BRIEF PROCESS STEPS	7
3.3	OUTPUT & DISCHARGING METHOD	7
4.0	PRODUCTIVITY REQUIREMENT	7
4.1	DESIRED/ SUGGESTED CAPACITY	7
4.2	STANDARD BATCH SIZE	7
4.3	CHANGE OVER TIME	7
4.4	OTHER PRODUCTIVITY REQUIREMENT	7
5.0	CONTAINMENT	7
6.0	GMP REQUIREMENTS	7
6.1	FAILURE MODE DETECTION	7
6.2	IN-PROCESS CONTROL	7
6.3	LEVEL OF INSTRUMENTATION	7
6.4	BATCH DATA DISPLAY AND RECORD PRINTING	8
6.5	GMP REQUIREMENTS (OTHERS)	8
6.6	SPECIFIC REQUIREMENTS	8
6.7	SPARES AND CONSUMABLES	8
7.0	CONSTRAINTS	8
7.1	EQUIPMENT LOCATION AND AVAILABLE SPACE	8
7.2	AVAILABLE UTILITY	8
8.0	ABBREVIATION	8
9.0	REVISION INDEX	9

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00



URS Annexure List:

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

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00



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			
Mr. Yogesha M J	Process Engineer	<i>Yogesha M J</i>	13-04-2016
Checked by			
Mr. Mahesh Kumar	Sr. Engineer – C&Q	<i>Mahesh Kumar</i>	13-04-2016
Approved by			
Dr. Harshad Mali	Lead Process engineer	<i>Harshad Mali</i>	13-04-2016

HLL Biotech Limited			
Name	Designation	Signature	Date
Reviewed by			
User Department (Measles) <i>K. RAONAKRISHNAN</i>	Dy. MANAGER.	<i>K. Raonakrishnan</i>	16-04-2016
User Department (Rubella bulk) <i>K. RAONAKRISHNAN</i>	Dy. MANAGER.	<i>K. Raonakrishnan</i>	16-04-2016
Project Engineering Department <i>A. Anand</i>	Manager	<i>A. Anand</i>	16-04-2016
QA Department <i>S. Jayakandan</i>	Sr. Manager, QA	<i>S. Jayakandan</i>	16-04-16
Approved By			
Head of User Department (Measles bulk) <i>D. R. Kumar</i>	DVP	<i>D. R. Kumar</i>	16-04-2016
Head of User Department (Rubella bulk) <i>D. R. Kumar</i>	DVP	<i>D. R. Kumar</i>	16-04-2016
QA Department <i>S. Suresh Babu</i>	DPM	<i>S. Suresh Babu</i>	16.04.2016
Authorized by			
CEO/HBL <i>Raman K. R.</i>	CEO	<i>Raman K. R.</i>	18-4-16

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU



nne pharmaplan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00

2.0 EQUIPMENT DESCRIPTION

The equipment described in this URS is a portable type & autoclavable 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
A. Major components required with the system are mentioned below:	
<ul style="list-style-type: none"> Filter housing: all product contact parts should be made of SS 316L and Surface finishing of the filter housing Inner surface – Ra <0.5 Ra[EP], external surface < 1.2 Ra. 	
<ul style="list-style-type: none"> Suitable provision to be provided for filter integrity testing. 	
<ul style="list-style-type: none"> The entire SS filtration housing should be sterilizable in autoclave at 121 °C 	
<ul style="list-style-type: none"> Diaphragm pressure gauge should be provided with TC ends above the SS housing bell and suitable end caps. 	
<ul style="list-style-type: none"> Inlet & 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. 	
<ul style="list-style-type: none"> 1/2" SS 316L grade sanitary diaphragm vent valve should be provided in the SS housing system for venting operation. 	
<ul style="list-style-type: none"> Maximum design pressure of filter housing must be of 10 bar. 	
<ul style="list-style-type: none"> Manual diaphragm valves of sanitary type at the feed inlet and filtrate outlet to be provided. 	
B. Cleaning: Cleaning of the system should be done manually.	
C. Sterilization: Sterilization of the system shall be done in autoclave.	

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 remained solution in the filter housing at the end of the process	
5	Integrity connector	For testing the integrity of the filter	

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

HBL HLL BIOTECH LIMITED A subsidiary of HLL Lifesciences Ltd. A Government of India Enterprise	User Requirement Specifications		
	Equipment/System	SS Filtration Housing Unit	
	Identification #	-	Document No. URS/SFU 02
	Effective Date	18-04-2016	Revision# 00

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.	Special Instruction a. If no comments against any specification should be considered as "NO" and 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.
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_17

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU



nne pharma plan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 Product inlet: Solution/Component is transferred from vessel to sterile filter unit either by pressure or by pump.	
3.2 Brief Process Steps	
3.2.1 The equipment will be used for filtration of the process solutions.	
3.3 Output & Discharging method	
3.3.1 The Filtrate will be collected into containers under LAF for further process	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
4.1.1 Low hold – up volume.	
4.1.2 The process piping inner diameter - vendor to specify.	
4.1.3 Filtration unit should be completely drainable.	
4.1.4 SS Housing should be suitable for code 7 type filters.	
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 Failure mode detection	
Not Applicable	
6.2 In –Process control	
Vent valve should be provided.	
6.3 Level of instrumentation	
Not Applicable	

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

ne pharmaplan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00



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 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

8.0 ABBREVIATION

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

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

User Requirement Specifications

Equipment/System	SS Filtration Housing Unit		
Identification #	-	Document No.	URS/SFU 02
Effective Date	18-04-2016	Revision#	00



9.0 REVISION INDEX

Revision	Date	Reason for revision
00	13-04-2016	First Draft for Client's Review

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 / Saunders