User Requirement Specifications

Sterile Filtration Train

Block Code	Area	Identification #	Description	Quantity
F2	Bacterial Vaccine Formulation	F2-SFT 01	2 x 10"; SS filter housing train to suit Code 7 type filter cartridge	1

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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 shall 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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2.0 EQUIPMENT DESCRIPTION

The equipment described in this URS is a portable type with skid support for carrying out the sterile 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
2.1 Scope of supply The skid mounted SS filtration train should be accommodated with 2 No.s of SS Filter Housing Bell to suit 10 Inch, Code 7 filter cartridges.	
A. Major components required with the system are mentioned below:	
• The system should be of automatic in operations for SIP	
• Filter housing and Filter Cartridges for sterile filtration of the process solutions	
• Product contact parts should be made of SS 316L and Surface finishing of the filter Inner surface – Ra <0.5 Ra[EP], external surface < 1.2 Ra.	
• Suitable provision to be provided for filter integrity testing.	
• Diaphragm pressure gauge should be provided with TC ends above the SS housing bell and suitable end caps.	
• Inlet & Outlet ports should be provided with sterilizable diaphragm valves with TC clamps.	
• ¾" SS 316L grade sanitary diaphragm vent valve should be provided in the SS housing system for venting operation.	
• Maximum design pressure of filter housing must be of 10 bar(g).	
• Automatic diaphragm valves of sanitary type at the pure steam inlet to be provided.	
• Control valve should be provided at the inlet of steam to control the temperature during SIP.	
B. Cleaning: Cleaning of the system should be done semi-automatic / manual.	
C. Sterilization: Sterilization of the system shall be carried out with utility connections in the room	

The filtration unit should contain the following for operation of the equipment as required.

S. No.	Description	Purpose	Remarks
1	Product Inlet with TC end	For attaching to the pipe line	
2	Product outlet with TC end	For attaching to pipeline to transfer to container.	
3	Filter housing	SS316L filter housings for code 7 type filter cartridge.	
4	Drain valves	For draining the product and condensate remained in the filter housing at the end of the process	
5	Integrity connector	For testing the integrity of the filter	
6	Temperature	At the condensate outlet for temperature control during SIP	

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 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_TD_06

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 **Product inlet:** Solution/Component is transferred from vessel/container to sterile filter train.	
3.2 Brief Process Steps	
3.2.1 The equipment will be used for clarification and sterile filtration of process solutions.	
3.3 Output & Discharging method	
3.3.1 The Filtrate will be transferred to containers 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 System should be completely drainable.	
4.1.4 SS Housing should be compatible with 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 Process control	
6.1.1 Following parameters should be controlled automatically a) High Pressure b) High Temperature c) Low Pressure d) Low Temperature e) Sterilization time	

6.2 Failure mode detection

Not Applicable

6.3 In –Process control

- Sampling valve & vent valve should be provided.

6.4 Level of instrumentation

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

Parameters	Purpose	Type of Instrumentation	Remarks
Temperature	Monitor ,Indicate, Record and control the temperature	Temperature sensor	
Pressure	Monitor, Indicate, Record and control the pressure	Pressure sensor	

6.5 Batch data display and record printing

Vendor shall provide single loop relay based controller and Batch data to be printed for all process values and all parameters by using strip chart recorder

6.6 GMP requirements (Others)

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

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

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

6.7 Specific requirements

6.7.1 The SS filtration system should be completely drainable.

6.7.2 SIPT timer to be provided.

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

6.8 Spares and consumables

6.8.1 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

This equipment will be used in the following rooms of IVC Chengalpattu

1. **Buffer and Solution Preparation Room** of **Bacterial Vaccine formulation block**,
   Equipment Location:
   Floor: Ground Floor
   Room Area: 36 m2
   False ceiling height: 3.5 m
   Room temperature: 22±2 °C
   Relative Humidity: Not more than 55 %

7.2 AVAILABLE UTILITY

Compressed air @ 6-8bar _____(Report requirement)
Pure steam @ 2.5 bar _____ (Report requirement)

8.0 ABBREVIATION

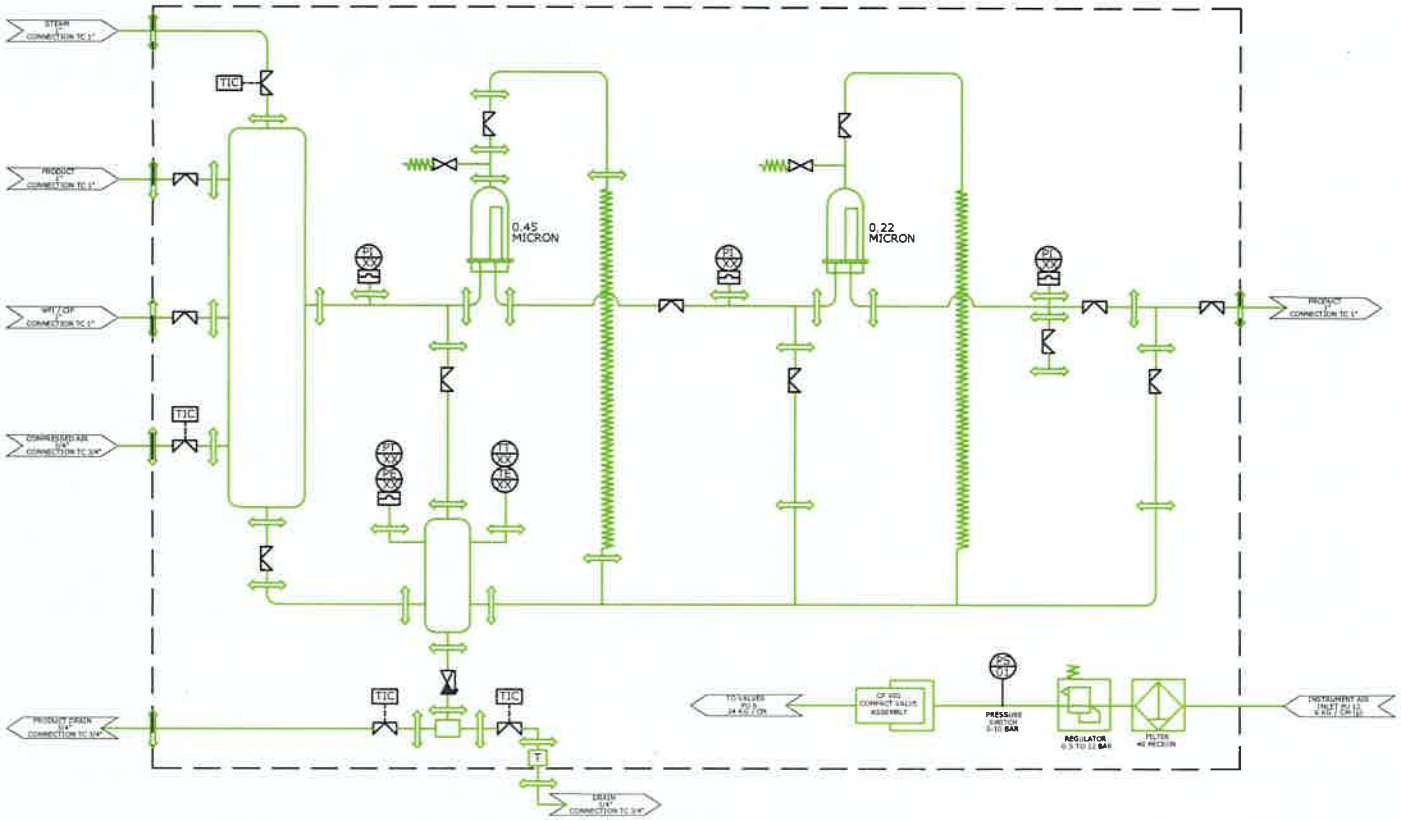
Abbreviation	Definition
ASME	American standard for manufacturing equipment
cGMP	Current Good Manufacturing Practice
HBL	HLL Biotech Limited
MOC	Material Of Construction
NNE	Novo Nordisk Engineering
NPI	NNE Pharmaplan India Ltd
NMT	Not more than
NWP	Nominal Water Permeability
TC	Tri-Clamp

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	09-06-2014	First Draft for Client's Review
01	05-07-2014	Updated as per MoM dated 05-07-2014

URS Annexure 1: List of Preferred Make of components

S.No	DESCRIPTION	MAKE
1	Pressure gauges	Wika/Denver/Negele
2	Diaphragm valve(Automatic)	Gemu /SED
3	Diaphragm valve(Manual)	Gemu /Novaseptic
4.	Steam trap	Steriflow /Sprirax
5.	Temperature sensor	Negale /Radix /E+H
6.	Temperature Transmitter	Radix/Yokogawa/E+H
7.	Pressure Transmitter	Wika / E&H



TE XX	TEMPERATOR SENSOR
PI XX	PRESSURE GAUGE
PT XX	PRESSURE TRANSMITTER
TT XX	TEMPERATURE TRANSMITTER
PE XX	PRESSURE SENSOR
	MANUAL DIAPHRAGM VALVE
	PREFILTER HOUSING
TIC	PNEUMATIC DIAPHRAGM VALVE
	NON RETURN VALVE
	FLEXIBLE HOSE
T	STEAM TRAP
	SEWAGE LOK CONNECTOR
	TRI CLOVER CLAMP

NOTE:- THIS P&ID IS ONLY FOR INFORMATION

Rev.	Date	Changed	Checked	Kind of revision	No. Of Prints	Date	Issued To

Client:
INTEGRATED VACCINES COMPLEX,
HLL BIOTECH LIMITED

Project No.: 120310
Location: CHENGALPATTU

nne pharmaplan
NNE Pharmaplan India Limited
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Description:
P&I DIAGRAM FOR
STERILE FILTERATION SYSTEM
(SEMI AUTOMATIC)

	Date	Name
Drawn	02.06.2014	SCEW
Checked	02.06.2014	SRKV
Approved	02.06.2014	VKKA
Scale- NTS	Units : mm	Size : A3

Drawing no: NPI/120310/EQP(PID)/SFU 01 | Rev. 00