nne pharmaplan®	User Requirement Specifications				
	Equipment/System	Sterile Filtration System			
	Identification	T-SFS 01	Document	URS/T-SFS 01	
	Effective Date	2014-01-02	Revision	05	

User Requirement Specifications
Sterile Filtration System

PROCESS CODE	AREA	EQUIPMENT TAG	QUANTITY	CONFIGURATION
T	TETANUS	T-SFS 01	1no.	10", Code 7 (5µm + 0.45µm + 0.22/0.2 µm) Filters

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URS Annexure List

URS Annex No.	Detail
1	Layout showing location of installation of the Sterile filtration System in the Final Filtration Room
2	List of preferred make of components

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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 "Revival of DPT Vaccines manufacturing Facility" (**Project number:-110831**) of Pasteur Institute of India, Coonoor under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of Pasteur Institute of India, and authorized by the appropriate Project Authority.

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Project Authority **Pasteur Institute of India**		

2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a "**Sterile Filtration System".** This is fully manual system and will be used for the final sterile filtration of the concentrated final toxoid bulk **(Tetanus vaccine).**

The system is considered to be a typical package units assembled and tested completely at the Vendor's workshop.

2.0.1 Scope of supply

The Skid mounted system (with castor wheel) with three housing with 5 µm+ 0.45µm + 0.22/0.2µm filters,

A. Major components required with the system are mentioned below:

- Code 7 ,10 inch (5 µm + 0.45µm + 0.22/0.2µm) filters with SS316L housing all pipelines and connections, which come in contact with the product should be made SS 316 L and electro polished with Ra<0.6 µ for product contact parts and Ra<1.2 µ for product non-contact parts
- Staubli connectors to be provided for the filters
- Pressure Gauges/ indicators
- Manual diaphragm valves (mainly for utilities like pure steam, compressed air)
- Peristaltic Pump (feed pump)
- Interconnecting sanitary process piping.
- Fittings (Such as Triclover clamps, steam traps, reducer (if required) etc)
- Pressure regulator for Compressed air
- Product sampling provision
- Instrumentation air assembly control (pre-filter, valve assembly etc)
- Skid mounted with complete assembly with lockable castor wheels with adjustable pads

B. TABLE 1

S. No.	Description	Purpose
1	Product Inlet with TC end	For attaching to the pipe line from the Pressure vessel
2	Product outlet with TC end	For attaching to flexi hose to transfer to Nalgene bottles sterile to sterile connection to be provided
3	Filter housing	SS316L filter housings for sterile grade filter of 0.45 µm and 0.22/0.2 µm.
4	Common drain line	For draining the product remained in the filter housing and the connected piping at the end of filtration. Also to drain the product from the vent of housing during initial purging of the product.
5	Staubli connector	For testing the integrity of the filter

C. **Clean In Place: CIP of the system shall be done** using Mobile CIP trolley(Once through) **with WFI and CIP recipe with the help of pump manual diaphragm valve, and pressure indicator.** The necessary controlling mechanism will be associated with the CIP trolley.

D. **Sterilization In Place:** Sterilization of the system shall be done by using the Mobile SIP Trolley.

Note: The following points which are there in the IRS(Installation Requirement Specifications) are not applicable for this equipment:

- 4.1.10 , 4.1.11, 4.1.13,4.1.17

- **Sec 5.1 Table 2**
  - **Sl.NO 2 and 3 :**FDA guidance for industry
  - Sl.NO 5 CE Conformity,
  - Sl.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
  - Sl.NO 8 ISO 14664
  - Sl.NO 9 ISO 8362
- Sec 5.4.1
- Sec 5.6

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. I n 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 become necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or an 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 HLL

	before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_110831_IRS_PII_01
XII.	Refer Tender document with URS; NPI/110831/EQP/TD/04

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 The final concentrated Tetanus bulk shall be passed through the Sterile filtration system with the help of Peristaltic pump and diaphragm valve arrangement.	
3.2 Brief Process Steps	
3.2.1 **The equipment has to be tested and operated according to Bio Safety level regulations.** a) Bulk shall be processed through the prefilter of 5 µm, 0.45µm and then processed with final sterile filter (0.22/0.2µm).	
3.3 Output & Discharging method	
3.3.1 After sterile filtration, the bulk shall be stored in the nalgene bottles and stored in the cold room at 2-8ºC	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested Capacity	
10 inch, code 7 (5 µm + 0.45µm + 0.22/0.2 µm filters)with SS 316L housing	
4.2 Standard batch size	
Not applicable	
4.3 Change Over Time	
4.3.1 Vendor shall ensure minimum time for change over	
4.3.2 To fix the right position of the format parts, they are to be marked with markings	

Specifications	Remarks
4.4 Others(if any)	
Not Applicable	
5.0 CONTAINMENT	
The System inlet and outlet connections shall be connected under Dedicated LAF (i.e. Class A) with the background Class B.	
6.0 GMP REQUIREMENTS	
6.1 Process control	
6.1.1 Following parameters shall be controlled manually	
a) Temperature of the sterilization	
b) The drain valve position and control.	
6.2 Failure mode detection	
a) Emergency stop activated (manual shut down)	
6.3 In –Process control	
6.3.1 Sampling valve should be provided to collect the samples at the end of filtration	
6.4 Level of instrumentation	
Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:	

Parameters	Purpose	Instrumentation
Temperature	Monitor and indicate the temperature (during SIP)	Temperature probe
Pressure	Monitor and indicate the pressure	Pressure gauge/ indicator
Flow rate	To control the flow of pressurized utility	Manual diaphragm valves

6.5	**Batch data display and record printing**	
	Refer IRS (Installation requirement Specification and Specific Instruction)	
6.6	**GMP requirements (Others)**	
6.6.1	Equipment must be designed for aseptic operation	
6.6.2	All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.	
6.7	**Specific requirements**	
	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points	
6.7.1	All ports should be attached with Sanitary Tri clamps	
6.7.2	All valves shall be sanitary type manually operated valves	
6.7.3	All valves shall be SS316L with diaphragm of PTFE backed EPDM and surface finish of Ra≤0.6 µm with Electro polished.	
6.7.4	Steam traps should be provided for the drain lines	
6.7.5	**Additional requirements**: Calibration of measuring instruments according to international standards, full-loop calibration is required for GMP and quality relevant instruments. The Supplier has to provide calibration protocols and guidelines for writing SOPs for recalibration.	
6.7.6	Performance criteria during FAT/SAT: a. Filter integrity test should be performed b. SIP of the whole system along with the compressed air inlet filter. c. Media fill with process simulation during SAT	

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the area of Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor.

Equipment Location (Sterile Filtration Room):

Block: Tetanus Block

Floor: Ground Floor

Room Size: 5300mm X 4775 mm

False Ceiling height: 3000 mm

Physical condition of the rooms:

Sterile Filtration Room (B2G043)

1. Room will be BSL 2
2. Class: EU Class “B”
3. Differential Pressure:55 Pa(Absolute)
4. Temperature maintained: 22±2 ºC
5. Relative Humidity: <55% RH

The equipment location is indicated in the relevant block of the layout enclosed as URS Annex-1.

7.2 Available Utility

7.2.1	Electricity: _____(Report Requirement)	
7.2.2	Water for Injection@2 bar(g): _____ (Report Requirement)	
7.2.3	Pure Steam@2.4 bar(g) _____ (Report Requirement)	
7.2.4	Compressed air@6-8 bar(g): _____(Report Requirement)	
	Note: Vendor to specify if there is any change in the utilities required	

8.0 ABBREVIATION

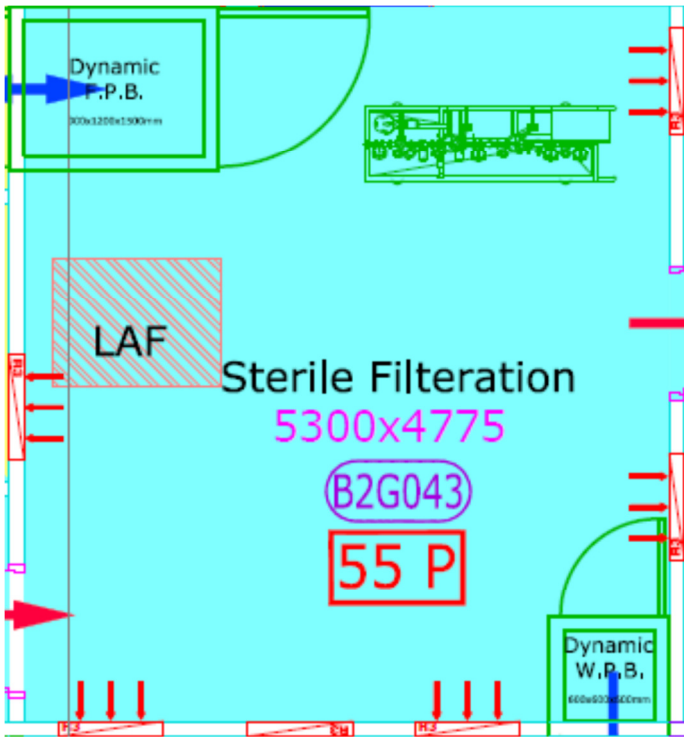
Abbreviation	Definition
^{0}C	Degree Centigrade
NPI	NNE Pharmaplan India Ltd
PII	Pasteur Institute of India
HLL	HLL Life care Limited
SS	Stainless steel
SFS	Sterile Filtration System

REVISION INDEX

Revision	Date	Reason for Revision
00	2011-12-14	First Draft
01	2012-05-18	Client's comment incorporated
02	2012-10-22	Format changed as per HLL requirement
03	2013-02-05	HLL comments incorporated, received during the workshop dated 22nd and 23rd January 2013
04	2013-05-10	As per the revised MOM received from HLL on 2013.03.18 by email
05	2014-01-02	Comments from HLL/PIIC incorporated_ email dated 2013.12.30

URS Annexure 1: LAYOUT POSITION

Room: (Tetanus Block): B2G043



URS Annexure 2: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
1	Steam trap	STERIFLOW/ITT
A	**MECHANICAL**	
2	Pressure gauges	WIKA/Denver/Negele
3	Pre air filter cartridge	Sartorius/ PALL/ Millipore
4	Filter cartridge	Sartorius/ PALL/ Millipore
5	Filter housing	Sartorius/PALL/ Millipore
6	Diaphragm valve(Manual)	GEMU/ Burkert
7	Ball valve(Manual)	Modentic/Saunders/Alfa laval