User Requirement Specifications
Precipitation Tank

Process Code	Area	Equipment code	Qty(Nos)	Capacity
D	Diphtheria	D-PPT 01	1	150 L (W.V.)
T	Tetanus	T-PPT 01	1	150 L(W.V)

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URS Annexure List

URS Annex No.	Detail
1	A) Layout showing location of the Precipitation Tank in the Diphtheria block
	B) Layout showing location of the Precipitation Tank in the Tetanus block
2	P&ID as separate URS annexure
3	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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2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a "Precipitation Tank". The equipment shall be used for the precipitation of concentrated toxoid in two stages of precipitation The Equipment shall be mobile type and should have legs fitted with anti-static castor wheels for easy transportation.

The Tank shall be suitable to take water for injection (WFI) of 85°C and pure steam @121ºC for SIP and mix other pre-weighed materials. Design, function and control of the unit have to be GMP compliant. The general design must be hygienic, with no dead legs and no air pockets.

2.0.1 **The equipment should consist of the following parts in order to run operation smoothly.**

S. No.	Description	Purpose	MOC
1	Shell	For holding and precipitation of toxoid	SS316L
2	Top closure	Torispherical dish	SS316L
3	Bottom closure	Torispherical dish	SS316L
4	Insulation	To avoid heat loss	Mineral wool
5	Cladding	To avoid the heat dissipation onto outer surface of the vessel	SS304
6	Magnetic mixer (bottom mounted)	To mix up the contents	SS316L
7	Height/Diameter Ratio	1.2:1	-

2.0.2 **Design Specifications:**

S. No.	Area	Geometric volume	Maximum working volume	Quantity
1	Diphtheria	200L (Vendor to confirm)	150L	1 no
2	Tetanus	200L (Vendor to confirm)	150L	1 no

2.0.3 **Vessel Specifications:**

SI.NO	Description	Specification
1	Min mixing volume	*Vendor to specify*
2	Working temperature range	$20^{o}C$ – $134^{o}C$
3	Surface Finish	Internally Electro polished up to Ra ≤0.8 µm (mirror finish) (For valves Mechanically polished up to Ra ≤0.8 µm)
		Internal finish of the interconnecting piping: Ra < 0.8 µm
		Externally Mechanically polished up to Ra ≤1.2 µm (matte finish)

2.0.4 The general design must be hygienic, with no dead legs and no air pockets. Following are the general requirements for a vessel:

a) **Port for Toxoid:** The toxoid from the Nalgene bottles shall be transferred into the Precipitation tank through the addition port of 1.5 inch with TC end.

b) **Port for Ammonium Sulphate addition :**

- For D-PPT 01: The 22% & 36% Ammonium Sulphate shall be added into the precipitation tank
- For T-PPT 01: The 12% & 24% Ammonium Sulphate shall be added into the precipitation tank

c) **Port for Acid/Alkali Addition:** Acid/ Alkali will be added manually to the precipitation tank

d) **Spray ball:** The port with fixed type Spray ball covering the entire area with 360^0 shall be provided on the top dish for the addition of CIP solution and WFI.

e) **Pressure :** Pressure of the vessel during process and SIP shall be monitored by the following:

- Diaphragm Pressure gauge for vessel

f) **Rupture disc:** It should be mounted on top of the buffer preparation vessel to relieve excess pressure during operations.

g) **Mixer:** The vessel shall be designed with bottom mounted GMP mixer as per process requirement.

- Variable speed 40-500 rpm. motor with magnetic drive. Open end of the motor shaft have a flange fitted with a circular magnet.
- Bottom mounted, magnetically coupled.
- Magnetic mixer, suitable for liquids up to Temp 134°C
- On/ off switch shall be provided

h) **Inlet/Exhaust Line:** The vent line includes

- A single sterile vent filter (0.2/0.22µm) with SS housing & a manual diaphragm valve.
- Compressed air inlet for vent filter
- Air PRV with filter should be provided

i) **Sampling valve:** It should be flush welded zero dead lag valve without steaming provision.

j) **Tank bottom valve:** It is Zero Dead Leg type valve. It shall be directly welded to vessel bottom centrally, having a PTFE diaphragm.

k) **CIP (Clean – In – Place):** The vessel shall be CIPed by using mobile CIP trolley.

- SS 316L spray ball shall be provided for cleaning of the vessel and all the nozzles on the top dish and nozzles, ports on the vessel

l) **SIP (Sterilization – In – Place)**: The Precipitation tank shall be designed for SIP using mobile SIP Trolley.

The following principles will be applied for SIP of the system:

- The exhaust air filters to be sterilized along with the vessel.
- SIP should be manually controlled.

m) **Controller:** - Single loop Relay based Controller shall be provided.

2.0.5 **Nozzle schedule**

1. **Top dish:**
   - Light/sight glass-1 No.
   - Hand hole-1 No.
   - Spray ball-1 No.
   - Rupture Disc-1 No.
   - Pressure gauge-1 No.
   - TC Spare part-1 No.
   - Inlet/Exhaust port with sterile vent filter(1 R 6" 0.2µm PTFE))-1 No.

2. **Upper wall side:**
   - Addition port for toxoid- 1No- 1.5inch with TC end
   - Addition port for ammonium sulphate – 1 No.
   - Port for acid/ alkali addition– 1 No.
   - Vertical view glass(with level marking)-1 No.

3. **Lower Wall side**
   - Sampling valve- 1 No.

4. **Bottom dish:**
   - Tank bottom valve- 1 No.
   - Port for Magnetic mixer- 1 No.

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
- Sec 5.1
- SI.NO 5 CE Conformity,
- SI.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
- SI.NO 8 ISO 14664
- SI.NO 9 ISO 8362
- Sec 5.4.1

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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 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 vendors' 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 Specifications and Specific Instructions" with URS NPI/110831/EQP/IRS 01
XII.	Refer tender document NPI/110831/EQP/TED/07

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 The vessel shall be used for two stages of precipitation.	
3.1.2 Concentrated toxoid shall be transferred into the Precipitation tank from the Nalgene bottles under Mobile LAF using peristaltic pump (Pump - vendor's scope).	
3.1.3 Required concentration of Aluminium Sulphate solution is added into the vessel during precipitation Stage I	
3.1.4 Required concentration Aluminium Sulphate solution is added into the vessel during precipitation Stage II	
3.2 Brief Process Steps	
A) **The tanks have to be designed to precipitate the toxoid transfer and to transfer respectively in sufficient quantity and quality.**	
3.2.1 Precipitation of the toxoid -Stage I	
3.2.2 Mixing is accomplished by using the bottom magnetic mixer.	
3.3 Output & Discharging method	
3.3.1 The precipitated product shall be transferred into the 2 L Nagene bottles(12 Nos)	
3.3.2 The product is centrifuged in 2 different Refrigerated centrifuges (6 No. of Nalgene bottles each)	
3.3.3 The supernatant from the 2 Centrifuges shall be collected in 20 L Nalgene bottles and transferred again into the precipitation tank for Precipitation Stage II. The steps from 3.1.4 to 3.3.2 shall be repeated	
3.3.4 The supernatant after centrifugation (precipitation stage II) shall be transferred to the next process steps	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
See **Table 2.0.2**	
4.2 Standard batch size	
See **Table 2.0.2**	
4.3 Change Over Time	
Not Applicable	
4.4 Others(If any)	
Not Applicable	

Specifications	Remarks
5.0 CONTAINMENT	
Not Applicable	
6.0 GMP REQUIREMENTS	
6.1 Process control	
The equipment must operate and control the following process parameters.	
6.1.1 Adjustable Mixer speed during the process (VFD shall be provided).	
6.2 Failure mode detection	
6.2.1 Mixing speed is out of set range	
6.3 In – Process control	
6.3.1 Should have provision for sampling of product solution.	
6.3.2 Should have provision of indication of Mixer speed	
6.4 Level of instrumentation	

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

Parameter	Purpose	Type of control and Instrumentation
Speed	To control Magnetic mixer speed	Variable frequency drive(VFD) with indicator
Pressure	To monitor the pressure during process and SIP	Diaphragm Pressure gauge

6.5 Batch data display and record printing	
Refer IRS(Installation requirement Specification and Specific Instructions)	
6.6 GMP requirements (Others)	
6.6.1 All nozzle connection shall be sanitary type and special attention shall be given in shape and dimension of the nozzle and connection to realize efficient cleaning and steaming process.	
6.6.2 All nozzles shall be flushed to the wall on closure.	
6.6.3 Nozzle length shall be minimized (less than 2D) to avoid cold spot during steam sterilization.	
6.6.4 Bottom discharge and sampling valve shall be zero dead leg type.	

	Specifications	Remarks
6.7	**Specific requirements**	
6.7.1	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.	
6.7.2	Nozzle shell shall be seamless.	
6.7.3	Nozzles, adaptors, instrument shall comply to ASME BPE compliant.	
6.7.4	Total motor drive assembly with SS304 cover.	
6.7.5	Vendor Shall provide FRL's (Filters, Regulators, Lubricators)	
6.7.6	From user point to the equipment, food grade SIPable flexible hose (2 m, 2 Nos) with 1 inch TC end to be provided.	
6.7.7	From the equipment to the drain, food grade SIPable flexible hose with 1 inch TC end of minimum 3 m length to be provided- 2 nos	
6.7.8	**Design Considerations:** 6.7.7.1 Shell working Pressure- FV to 2.5 bar(g) 6.7.7.2 Shell working Temperature- 20-134°C 6.7.7.3 Shell sterilization Temperature- 121°C 6.7.7.4 Shell design Pressure- Vendor to specify 6.7.7.5 Shell design Temperature- Vendor to specify	
6.7.9	The equipment shall be easily accessible for cleaning the product non-contact part at maintenance side of the equipment.	
6.7.10	Vessel shall be on 3 legs MOC: SS 304 with anti-static double-roll lockable castor wheels for easy transportation	
6.7.11	**Performance criteria during FAT/SAT:** a. Spray ball coverage test during FAT b. Thermal mapping c. All FAT/SAT IQ,OQ as per IRS	
7.0	**CONSTRAINTS**	
7.1	**Equipment location and available space**	
a)	This equipment will be installed in the **Diphtheria block** of the Revival of DPT Vaccine manufacturing facility, PII, Coonoor as follows. **Floor:** Ground; **Room No:** B1G060 **Plant:** Diphtheria bulk manufacturing **Room dimension :** 4.8 m x 6.50 m **False ceiling height**: 3 m **Physical condition of the room:**	

Specifications	Remarks
1. Room will be NON-BSL 2 2. Class: EU Class “C” 3. Differential Pressure:35 Pa 4. Temperature maintained: 22±2 ºC 5. Relative Humidity: <55% RH b) This equipment will be installed in the **Tetanus block** of the Revival of DPT Vaccine manufacturing facility, PII, Coonoor as follows. **Floor:** Ground; Room No: B2G039 **Plant:** Tetanus bulk manufacturing **Room dimension :** L x W**:** 7.4 x 7.23 m **False ceiling height:** 3 m **Physical condition of the room:** 1. Room will be NON-BSL 2 2. Class: EU Class “C” 3. Differential Pressure:30 Pa 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 Avaialable Utility	
7.2.1 Compressed Air @ 8 bar _____ (Report requirement)	
7.2.2 WFI (Hot loop) @2 bar_____ (Report requirement)	
7.2.3 Pure steam@2.5 bar _____ (Report requirement)	
7.2.4 Electricity : 1.5 kW (Report requirement)	

8.0 ABBREVIATION

Abbreviation	Definition
PII	Pasteur Institute Of India
PPT	Precipitation Tank
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
HLL	HLL Life care Limited
NPI	NNE Pharmaplan India Ltd

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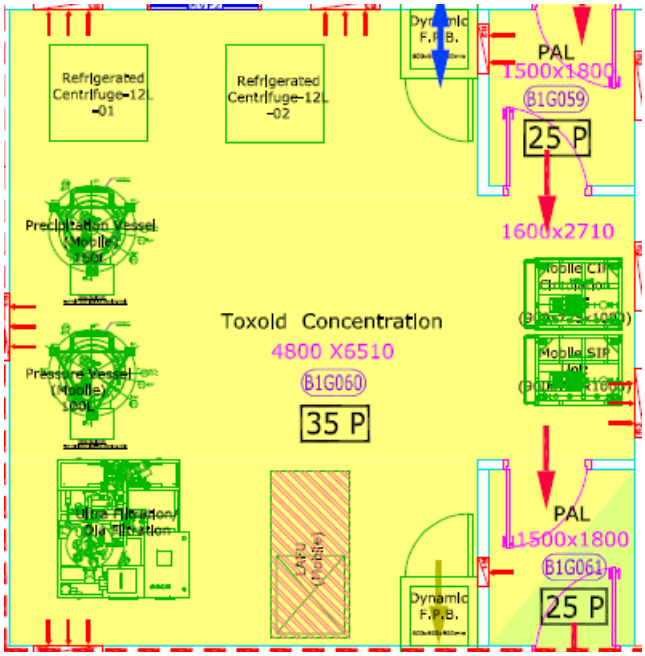
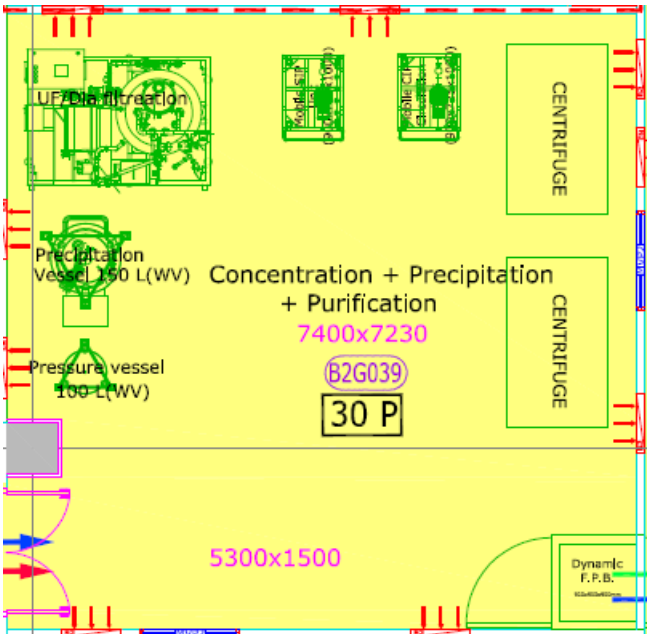
REVISION INDEX

Revision	Date	Reason for Revision
00	2012-06-01	First Draft for Client's Review
01	2012-12-10	Format changed as per HLL requirement
02	2013-06-27	As per the MOM dated 2013-05-28 & 2013-05-29
03	2013-09-25	As per the discussion with HLL on Video Con on 2013-09-11 ,2013-09-12 and comments received on 2013-09-20
04	2013-10-28	Revised as per comments received on URS by email on 2013-10-23
05	2013-11-20	Revised as per comments received on URS by email on 2013-11-18
08	2014-01-28	URS's Consolidated as per telephonic confirmation between NNE and HLL
09	2014-07-02	Revised as per the discussion with HLL on 2014-06-19 and 2014-06-20

URS Annexure 1: LAYOUT A Room No: B1G060



URS Annexure 2: LAYOUT; Room No: B2G039



URS Annexure 3: List of preferred make of components

SI.NO	COMPONENTS	MAKE
	INSTRUMENTATION	
1.	Temperature Sensor/transmitter	Radix/ NEGELE
2.	Steam trap	STERIFLOW/ITT/Spirax
	MECHANICAL	
3.	Pressure gauge	WIKA/Denver/Negele
4.	Air filter cartridge	Sartorius/PALL / Millipore
5.	Spray ball	HAKE
6.	Diaphragm valve	GEMU/Burkert/ITT/SED/saunders
7.	Ball valve	Modentic/Saunders/Alfa laval
8.	Sampling valve	GEMU/Burkert/ITT/SED/saunders
9.	Tank bottom valve	GEMU/Burkert/ITT/SED/saunders
10.	Rupture disc	Zook/Elfab/fike
11.	Air-PRV	Festo/SMC
12.	GMP mixer	Alfa Laval/Novaseptic/ Roplan
13.	Flexible hose	AB Synthetic/ AMI Polymer/Venair
	PNEUMATIC	
14.	Diaphragm valve(Automatic)	GEMU/Burkert/ITT/SED/saunders
15.	Angle seat valve(Automatic)	GEMU/Burkert/ITT/SED/saunders
	ELECTRICAL	
16.	Lamp	PAPENMEIER