User Requirement Specifications
Collection vessel

Process Code	Area	Equipment code	Qty(Nos)	Capacity
F	Formulation (Component collection and component Mixing)	F-COV 01	1	100 L (W.V)
F	Formulation (Component collection and component Mixing)	F-COV 02	1	100 L (W.V)

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the collection vessel in the Formulation 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 “Collection vessel”.

The vessel shall be used for the collection of gel and also for the preparation of thiomersal and EDTA solutions. The Vessel shall be suitable to take water for injection (WFI) of 30°/85°C. The vessel shall be used to collection and mix the raw materials.

The vessel shall be cylindrical having Flat top Openable hinged type and Torispherical bottom dish and shall be provided with vessel bottom valve for discharge.

The collection vessel shall be CIP able using Mobile CIP System

The Equipment shall be made SS316L for product contact parts including vessel, inlet and out let nozzles, valves, piping interconnection.

Design, function and control of the unit have to be GMP compliant.

2.0.1. TABLE 1

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

S. No.	Description	Purpose	MOC
1	Shell	To hold the material for mixing	SS316L
2	Top closure	Flat openable type	SS316L
3	Bottom closure	Torispherical dish	SS316L
4	Insulation	To avoid heat loss	Mineral wool
5	Cladding	To avoid the heat dissipation	SS304
6	Impeller (bottom mounted)	To mix up the contents motor shall be considered separately	SS316L
7	Height/Diameter Ratio	1.2:1	-

2.0.2. Design specifications

SI.NO	Identification	Geometric volume	Maximum working volume	Quantity
1.	F-COV 01	150 L	100 L	1 no
2.	F-COV 02	150 L	100 L	1 no

2.0.3. General vessel specification are as under :

SI.NO	Description	Specification
1.	Min mixing volume	*Vendor to specify*
2.	Working temperature range	20-134^{o}C
3.	Temperature control deviation	±0.5 ºC
4.	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 (matt finish)

2.0.4. The general design must be hygienic, with no dead legs and no air pockets. The collection vessel must be fully drainable. This Vessel must be a floor-standing type with mounting legs on caster wheels. Following are the general requirements for a vessel**:**

a) **Top dish:**

- Flat lid Openable- hinged type arrangement for addition of raw materials.

b) **Spray ball:** The port with detachable/removable type spray ball covering the entire area with 360^0 shall be provided on the top dish for the addition of WFI and CIP solution from CIP system.

c) Mixer: The vessel shall be designed with impeller and motor with trolley should be considered separately.

d) **Inlet/Exhaust Line:** The inlet/exhaust line shall be provided with

- Compressed air inlet for vent filter
- Air pressure reducing valve (PRV) (with filter).
- A single sterile filter (0.2/0.22 µm) with SS housing for both inlet and exhaust.

e) **CIP (Cleaning– In – Place)**: The vessel should have a provision CIP using mobile CIP trolley.

f) **Tank bottom valve:** Zero dead lag type-2way diaphragm valve.

2.0.5. Nozzle schedule

1. **Top dish:**
   - Light/sight glass-1 No
   - Spray ball-1 No
   - Spare part-1 No
   - Exhaust port with sterile vent filter(1 R 6" 0.2µm PTFE))-1 no
2. **Upper wall side:**
   - Vertical view glass(with level marking)-1 No
3. **Bottom dish:**
   - Tank bottom valve1 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:

1.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
2.	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.
3.	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.
4.	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.
5.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
6.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
7.	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.
8.	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.
9.	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.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
11.	Refer document "Installation Requirement Specifications and Specific Instructions" with URS NPI/110729/PIIC/IRS 01
12.	Refer the tender document NPI/110831/EQP/TD/07

Specifications		Remarks
3.0	**PROCESS DESCRIPTION**	
3.1	**Input & Charging method**	
3.1.1	Gel collection Vessel Gel from mixing vessel shall be charged into the vessels and stored	
3.1.2	Mixing Vessel The WFI at 80^0C-85^0C shall be added into the vessel. The raw material (Thimerosal or EDTA) shall be added respectively.	
3.2	**Brief Process Steps**	
3.2.1	The gel shall be stored and taken for further processing	
3.2.2	The raw materials (Thimerosal or EDTA) shall be mixed well with WFI	
3.3	**Output & Discharging method**	
3.3.1	Gel shall be taken out manually	
3.3.2	The prepared solution shall be transferred through the bottom discharge valve to the next process.	
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	
5.0	**CONTAINMENT**	
	Not Applicable	
6.0	**GMP REQUIREMENTS**	
6.1	**Process control**	
	Not Applicable	
6.2	**Failure mode detection**	
	Not Applicable	

Specifications	Remarks
6.3 In – Process control	
Not Applicable	
6.4 Level of instrumentation	
Not Applicable	
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 shall be zero dead leg type.	
6.6.5 Utility operation shall be preferably manual and valves shall be placed inside of aseptic area.	
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 Nozzle shell shall be seamless.	
6.7.2 Nozzles, adaptors, instrument shall be ASME BPE compliant.	
6.7.3 Total motor drive assembly with SS304 cover	
6.7.4 **Design Parameters:** 2.7.4.1 Shell working Pressure- FV to 2.5 bar(g) 2.7.4.2 Shell working Temperature- 20-134°C 2.7.4.3 Shell sterilization Temperature- 121°C 2.7.4.4 Shell design Pressure- Vendor to specify 2.7.4.5 Shell design Temperature- Vendor to specify	
6.7.5 From user point to the equipment, food grade SIPable flexible hose (2m- 2 No's) with TC end to be provided.	
6.7.6 All black utility non-sterile hoses are considered in vendor's scope (2m – 2 No's)	
6.7.7 From the equipment to the drain, food grade SIPable flexible hose with TC end of minimum 3 m length to be provided -2 No's.	
6.7.8 The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment	

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Specifications	Remarks
6.7.9 Vessel shall be on 3 legs MOC: SS 304 with double-roll lockable castor wheels for easy transportation. (for 100 L and 200L Vessels)	
7.0 CONSTRAINTS	
7.1 Equipments location and available space	
All equipments will be installed in the Formulation block of the **Revival of the DPT vaccine manufacturing facility at PII, Coonoor** as follows: **Floor:** Ground floor-Formulation; **Room No**: F1G038 **Room size:** 31m^2 **False ceiling height:** 3 m **Physical condition of the room:** 1. Class: EU Class "C" 2. Differential Pressure:35 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: NMT 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 Chilled Water@ 2 bar _____ (Report requirement)	
7.2.2 Compressed Air@8 bar _____ (Report requirement)	
7.2.3 WFI@ 2bar_____(Report requirement)	
7.2.4 Pure Steam@2.5 bar _____(Report requirement)	
7.2.5 Plant Steam@3-8 bar _____(Report requirement)	
7.2.6 Electricity :1.5 kW (Report requirement)	

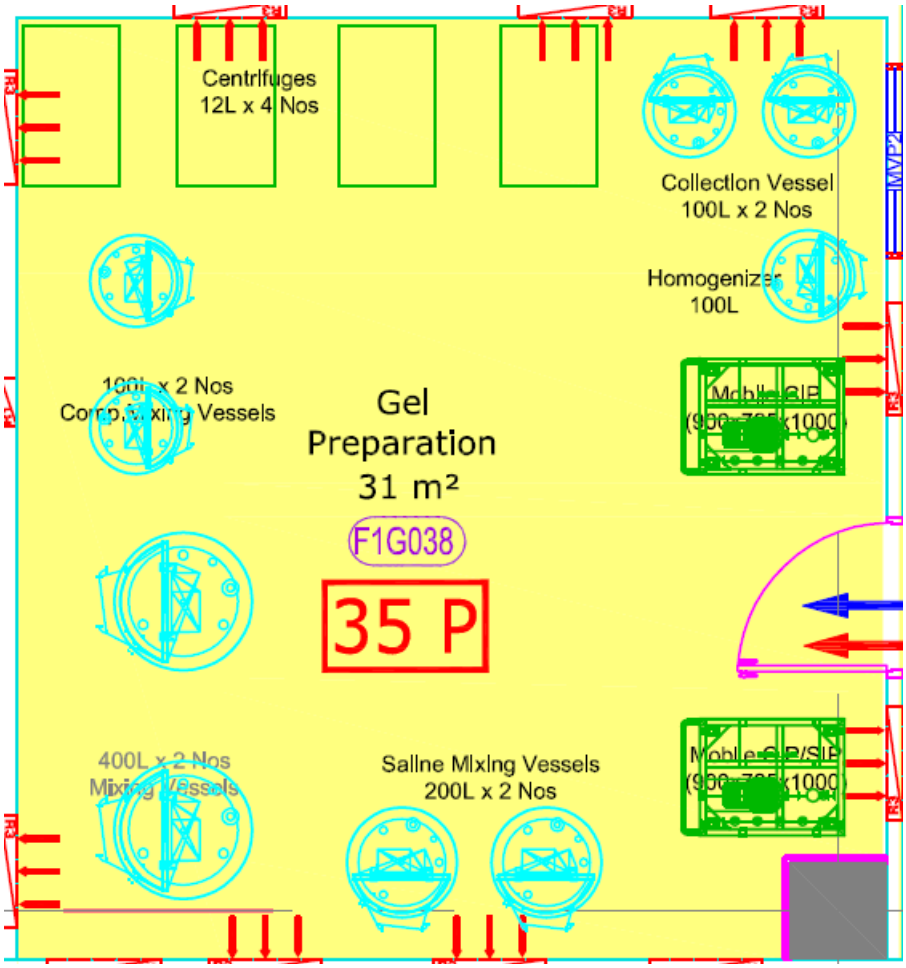
8.0 ABBREVIATION

Abbreviation	Definition
PII	Pasteur Institute Of India
COV	Collection Vessel
CIP	Clean In Place
SIP	Sterilization In Place
PII	Pasteur Institute Of India
cGMP	Current Good Manufacturing Practices
HLL	HLL Life care Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization
EUGMP	European Union Good Manufacturing Practices
NMT	Not more than

REVISION INDEX

Revision	Date	Reason for Revision
00	2014-10-15	First Draft for Client's Review

URS Annexure 1: LAYOUT; Room No: F1G038



URS Annexure 3: List of preferred make of components

	MECHANICAL	
1.	Pressure gauges	WIKA/DENVER/NEGELE
2.	Filter cartridge	SARTORIUS/PALL / MILLIPORE
3.	Spray ball	HAKE
4.	Diaphragm valve	GEMU/Burkert/ITT/SED/saunders
5.	Ball valve	MODENTIC/SAUNDERS/ALFA LAVAL
6.	Vessel bottom valve	NOVASEPTIC/GEMU
7.	Flexible hose	AB SYNTHETIC/ AMI POLYMER/Veniar
8.	Magnetic Mixer	NOVASEPTIC/ALFA LAVAL/ROPLAN
9.	Air PRV	FESTO/JANATICS PNEUMATICS
	PNEUMATIC	
10.	Diaphragm valve(Automatic)	GEMU/Burkert/ITT/SED/saunders
	ELECTRICAL	
11.	Lamp	PAPENMEIER