User Requirement Specifications
Gel Sterilization vessel

Process Code	Area	Equipment code	Qty(Nos)	Capacity
F	Formulation	F-GSV 01	1	100 L(G.V)

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Gel sterilization 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 Gel sterilization vessel with 60 L working volume shall be cylindrical having Torispherical top and bottom dish and shall be provided with flush bottom valve for discharge. The vessel shall be mounted on Stainless steel pipe legs and caster wheels. The gel sterilization vessel is used in the formulation block to sterilize the homogenized gel (in-situ).

The vessel shall be suitable to take water for injection (WFI) of 85°C for CIP and Plant steam @121ºC for SIP and other pre-weighed materials.

The gel sterilization vessel shall be CIP/SIPable.

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 cGMP compliant.

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

S. No.	Description	Purpose	MOC
1.	Shell	Cylindrical, To sterilize the gel	SS316L
2.	Top closure	Flat Lid	SS316L
3.	Bottom closure	Torispherical dish	SS316L
4.	Jacket	For temperature maintenance	SS304
5.	Insulation	To avoid heat loss	Mineral wool
6.	Cladding	To cover the jacket and to avoid the heat dissipation onto outer surface of the vessel	SS304
7.	Mixer	Bottom mounted GMP Mixer	SS316L
8.	Height/Diameter Ratio	1.2:1	-

2.0.2 General vessel specification are as under :

Sl.NO	Description	Specification
1.	Geometric volume	100L
2.	Maximum working volume	60 L
3.	Quantity	1 No
4.	Surface Finish	Internally Electro polished up to Ra ≤0.6 microns(mirror finish)
		Internal finish of the interconnecting piping: Ra < 0.6 µm
		Externally Mechanically polished up to Ra ≤1.2 microns(matt finish)

2.0.3 The general design must be hygienic, with no dead legs and no air pockets. The mixing vessel must be fully drainable.

Following are the general requirements for a vessel:

a) **Gel Addition:** Homogenized gel will be added into the gel sterilization vessel through the port provided.

b) **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 WFI and pure steam.

c) **Inlet/Exhaust line:** The vent /exhaust line shall be provided with

- A single sterile inlet and exhaust filter (0.2/0.22 micron) with SS housing.
- Compressed air inlet for vent filter
- Air PRV (with filter)

d) **Temperature:** To maintain the temperature during gel sterilization, temperature sensor with transmitter shall be provided.

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

- Diaphragm Pressure gauge for vessel

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

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

h) **Sampling Valve:** Separate valve with insitu sterilization, Zero Dead Leg type directly welded to vessel lower wall side having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization.

i) **Flush Bottom Valve:** It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization.

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

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

k) **SIP (Sterilization – In – Place)**: The In-situ gel sterilization vessel shall be designed for SIP.

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

- The exhaust air filters shall be sterilized along with the vessel.
- The sampling valve, flush bottom valve shall be sterilized independently.
- The sensors should be reusable and sterilizable type.
- Pressure regulating valve for pure steam line
- SIP should be fully automatic.

l) **Controller:** - Relay based controller with strip chart recorder should be provided.

2.0.4 Nozzle schedule

1. Top dish:

- Light/sight glass-1 No.
- Hand hole -1 No.
- Spray ball -1 No.
- Pressure gauge -1 No.
- Non Sterile addition Port
- Rupture disc -1 No.
- TC Spare part -1 No.
- Inlet/Exhaust port with sterile filter(1 R 6" 0.2µ PTFE)) -1 No.

2. Upper wall side:

- Jacket outlet-1 No.
- Vertical view glass (Level Marking) -1 No.

3. **Lower wall side:**
   - Sampling valve with provision for steam sterilization- 1 No.
   - Jacket inlet -1 No.
   - Temperature sensor-1 No.

4. **Bottom dish:**
   - Flush bottom valve provision for separate steam sterilization-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

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

nne pharmaplan®	User Requirement Specifications			
	Equipment/System	Gel Sterilization Vessel		
	Identification	F-GSV 01	**Document**	URS/F-GSV 01
	Effective Date	2014-07-02	**Revision**	06

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 Homogenised gel from homogeniser vessel shall be transferred to gel sterilization vessel using mobile pressure vessel by air pressure.	
3.2 Brief Process Steps	
3.2.1 The gel is sterilized in the vessel at a temperature of 121^0C by means of circulation of plant steam in the jacket.	
3.3 Output & Discharging method	
3.3.1 Sterile gel from gel preparation vessel is collected in sterile bottles (under LAF) and stored.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
100 L Geometric volume	
4.2 Standard batch size	
60L Working volume	
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	
The equipment must operate and monitor the following process parameters:	
6.1.1 Temperature of the gel	
6.1.2 Adjustable mixer speed (VFD shall be provided)	
6.2 Failure mode detection	
Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process: (if it exceeds by 0-10% (i.e. tolerance limit) of the set point value):	

Specifications	Remarks
6.2.1 Mixing speed is out of set range	
6.2.2 Temperature is out of set range	
6.2.3 Abrupt change in temperature in a particular time	
6.3 In – Process control	
6.3.1 Should have provision for sampling of gel.	
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
Temperature	To monitor, indicate and control the vessel temperature	Temperature transmitter
Pressure	To monitor, indicate the pressure inside the vessel	Diaphragm pressure gauge
RPM	To control the speed of bottom magnetic mixer	Variable frequency drive with indicator

6.5 Batch data display and record printing	
Batch data printing by using real time printer and for trends strip chart recorder to be provided	
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, with flushed type intergrated.	
6.6.5 Steam traps shall be provided where ever required at the system.	
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 comply with ASME BPE compliant.	

Specifications	Remarks
6.7.3 Total motor drive assembly with SS304 cover	
6.7.4 The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment with 100 % drainability.	
6.7.5 Vessel shall be on 3 legs MOC: SS 304 with double-roll lockable castor wheels with anit-static property for easy transportation.	
6.7.6 From user point to the equipment, food grade SIPable flexible hose (2 m, 2 Nos) with TC end to be provided.	
6.7.7 From the equipment to the drain, food grade SIPable flexible hose with TC end of minimum 2 m length to be provided.	
6.7.8 **Design Parameters:** 4.7.8.1 Shell operating pressure- FV to 2.0 bar(g) 4.7.8.2 Shell operating temperature- 20-134°C 4.7.8.3 Shell sterilization temperature- 121°C 4.7.8.4 Jacket operating temperature-0-135°C 4.7.8.5 Jacket design temperature-0-150°C 4.7.8.6 Jacket working pressure-FV to 3.0 bar 4.7.8.7 Jacket design pressure-FV to 4.0 bar 4.7.8.8 Shell design pressure- Vendor to specify 4.7.8.9 Shell design temperature- Vendor to specify	
6.7.9 **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	
This equipment will be installed in the Formulation block of the **Revival of DPT Vaccine manufacturing facility, at PII, Coonoor** as follows: **Floor:** Ground floor –Formulation; Room No: F1G059 **Room size :** 9 m2 **False ceiling height:** 3.0 m **Physical condition of the room:** 1. Class: EU Class “B” 2. Differential Pressure:45 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: <55 % RH The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex 1.**	

Specifications	Remarks
7.2 Available Utility	
7.2.1. Plant steam @ 3-8 bar _____(Report requirement)	
7.2.2. Pure steam@2.5 bar_____(Report requirement)	
7.2.3. Chilled water @2 bar_____(Report requirement)	
7.2.4. Cooling Water @3 bar _____ (Report requirement)	
7.2.5. Compressed Air@8 bar_____(Report requirement)	
7.2.6. Electricity:1.5 kW(Report requirement)	

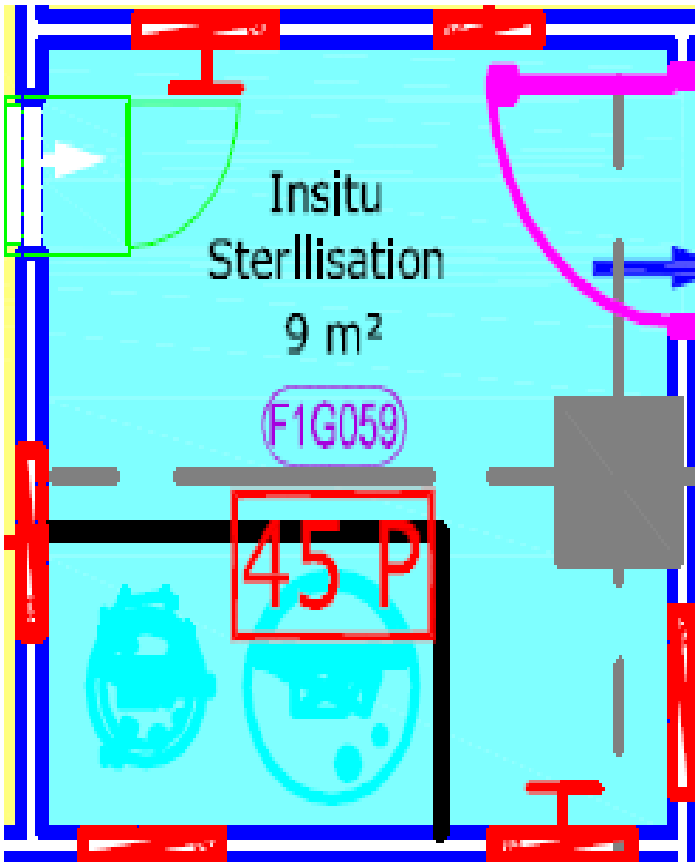
8.0 ABBREVIATION

Abbreviation	Definition
PII	Pasteur Institute Of India
GSV	Gel Sterilization Vessel
CIP	Clean In Place
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
HLL	HLL Lifecare Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization

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	2013-09-23	As per the discussion with HLL on Video Con on 2013-09-11 ,2013-09-12 and comments received on 2013-09-20
04	2014-01-02	Revised as per the discussion with HLL on Video Con on 2014-01-02
05	2014-01-21	Revised as per comments received on URS by e-mail on 2014-01-17
06	2014-07-02	Revised as per the discussion with HLL on 2014-06-19 and 2014-06-20

URS Annexure 1: LAYOUT ; Room No: F1G059



URS Annexure 3: List of preferred make of components

SI.NO	COMPONENTS	MAKE
	INSTRUMENTATION	
1.	Temperature Sensor/transmitter	Radix/ NEGELE /WIKA
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 / ITT/SED/Burkert/Saunders
7.	Ball valve	Modentic/Saunders/Alfa laval
8.	Sampling valve	GEMU / ITT/SED/Burkert/Saunders
9.	Tank bottom valve	GEMU / ITT/SED/Burkert/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 / ITT/SED/Burkert/Saunders
15.	Angle seat valve(Automatic)	GEMU / ITT/SED/Burkert/Saunders
	ELECTRICAL	
16.	Lamp	PAPENMEIER