User Requirement Specifications
Pressure vessel

Block Code	Area	Identification #	Quantity (No.)	Capacity (WV)
F1	Viral Vaccine Formulation-Measles	F1-PRV-01	1	5 L
		F1-PRV-02	1	10L
		F1-PRV-03	1	20L
F1	Viral Vaccine Formulation-Rabies	F1-PRV-04	1	5 L
		F1-PRV-05	1	10 L
		F1-PRV-06	1	20 L
F2	Bacterial Vaccine Formulation	F2-PRV-01	1	20 L
B4	Rabies Vaccine bulk	B4-PRV-01	1	5 L
		B4-PRV-02	1	10 L
		B4-PRV-03_06	4	20 L
		B4-PRV-07 & 08	2	50L
		B4-PRV-09	1	100L
Q1	Quality Control	Q1-PRV-01	1	5 L
		Q1-PRV-02	1	10L
		Q1-PRV-03	1	20L

Table of Contents

1.0 APPROVAL SIGNATURES 4

2.0 EQUIPMENT DESCRIPTION 5

2.1 General Description 5

2.2 General Nozzle Schedule 5

3.0 PROCESS DESCRIPTION 7

3.1 Input & Charging method 7

3.2 Brief Process Steps 7

3.3 Output & Discharging method 7

4.0 PRODUCTIVITY REQUIREMENT 7

4.1 Change Over Time 7

4.2 Other Productivity Requirement 7

5.0 CONTAINMENT 7

6.0 GMP REQUIREMENTS 7

6.1 Process control 7

6.2 Failure mode detection 7

6.3 In – Process control 7

6.4 Level of instrumentation 7

6.5 Batch data display and record printing 7

6.6 GMP requirements (Others) 7

6.7 Specific requirements 8

6.8 Spares and consumables (If Applicable) 8

7.0 CONSTRAINTS 8

7.1 Equipment location and available space 8

7.2 Available Utility 8

8.0 ABBREVIATION 8

9.0 REVISION INDEX 9

URS Annexure List

URS Annex No.	Details
1	List of preferred MAKE of components

1.0 APPROVAL SIGNATURES

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 & QA and authorized by the appropriate Project authority.

NNE Pharmaplan India Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Ms. Niharika Ruhela	Technical Assistant-Biotech	for Kiran	20-10-2014
Checked by			
Ms. Bincy Joseph	Assistant Manager-Biotech		20.10.2014
Approved by			
Mr. Vikas Katial	GM - Head COC Vaccines		20.10.2014

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
P. NAVIN KUMAR	DM-VIRAL VACCINE-FORMULATION		30.10.2014
K. RADHAKRISHNAN	DM. PRODUCTION		30.10.2014
CH. LAKSHMI PUNNARAO	DM. Formulation		30.10.2014
SANJEEV KUMAR R	M.Q.C.		30.10.2014
VIGNESHKARAN T	AM-PROJECTS		28-10-2014
Approved By			
Dr. Nivedita Veerbadran	project head (I-V)		31/10/14
Dr. R. KUMARAVEL	DVP-Production		30.10.2014
G. NARASIMHA REDDY	Sr. Manager		30.10.2014
R. SURESH BABU	DGM		31.10.2014
R. SURESH BABU	DGM		31.10.2014
Authorized by			
RAMANA K.R	CEO		03.11.2014

2.0 EQUIPMENT DESCRIPTION

The vessel shall be designed, constructed, built, installed and commissioned to hold solutions and should comply cGMP requirements.
The vessel should be autoclavable

The equipment should consist of following features in order to run operation smoothly.
Table 1

S. No.	Description	Purpose	MOC	Remarks
1.	Shell	Cylindrical to hold the product	SS316L	
2.	Top closure	Completely detachable flat lid	SS316L	
3.	Bottom closure	Tori spherical dish with skirt support	SS316L	

2.1 General Description

S No.	Description	Remarks
2.1.1	**Product transfer:** These autoclavable pressure vessels will be used for the preparation of media/buffers	
2.1.2	For 5 L and 10 L pressure vessel compact handle for lifting should be provided and a standard SS Skirt at the bottom. For holding 20 L, 50L, 100L vessel, SS 304 trolley mounted on a castor wheels made of polyurethane should be provided.	
2.1.3	**Surface finish:** All pressure vessels should be internally electro polished with <0.6 Ra finishing and externally should have < 1.2 Ra finishing.	

2.2 General Nozzle Schedule

S No.	Description	Remarks
2.2.1	**Ports required in the top lid:**	
	• Air inlet (I.e., provision for vent filter)	
	• Media outlet	
	• Safety release valve	
	• Port for diaphragm pressure gauge	
2.2.2	The top lid should be completely detachable ,Inlet & Outlet ports(air,product) should be provided with SS 316L hose barb adapter to suit 6mm to 8mm ID silicon tubes	

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**
  a. SI.NO 2 and 3 :FDA guidance for industry
  b. SI.NO 5 CE Conformity,SI.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
  c. SI.NO 8 ISO 14664,SI.NO 9 ISO 8362
- Sec 5.6

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications				HBL HLL BIOTECH LIMITED
	Equipment/System	Pressure Vessel			
	Identification #	-	**Document**	URS/PRV_01	
	Effective Date	03-11-2014	**Revision #**	02	

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. 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.
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 becomes necessary the item must be clearly stated.
4.	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.
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 HBL before submitting the quotes.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
11.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01
12.	Refer Tender document with URS; NPI_120310_EQP_TD_08

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

User Requirement Specifications

Equipment/System	Pressure Vessel		
Identification #	-	**Document**	URS/PRV_01
Effective Date	03-11-2014	**Revision #**	02

HBL HLL BIOTECH LIMITED

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 Components used for the preparation of solution are fed into vessel through a dip tube or by opening the top lid.	
3.1.2 Inlet and outlet ports for air and product should be provided with SS 316L hose barb adapter to suit 6mm ID silicone tube.	
3.2 Brief Process Steps	
3.2.1 NA	
3.3 Output & Discharging method	
3.3.1 Transfer of media/Buffer will be done by using sterile compressed air or peristaltic pump. Media outlet should be designed for complete drainability of solutions during operation.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Change Over Time	
NA	
4.2 Other Productivity Requirement	
NA	
5.0 CONTAINMENT	
NA	
6.0 GMP REQUIREMENTS	
6.1 Process control	
NA	
6.2 Failure mode detection	
NA	
6.3 In – Process control	
NA	
6.4 Level of instrumentation	
NA	
6.5 Batch data display and record printing	
NA	
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 sterilization process	

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. Vessel should be provided with compact handle for lifting and a standard SS Skirt at the bottom.	
6.7.2. Nozzles, adaptors, instrument shall comply with ASME BPE compliant.	
6.7.3. The equipment shall be easily accessible for cleaning	
6.7.4. Gaskets should be made up of food grade/ Silicone/ EPDM.	
6.7.5. Product contact parts should be fabricated with SS 316 L grade and all sanitary joints and connections to be sealed using PTFE/ silicone/ EPDM gasket.	
6.7.6. **Design Parameters:**	
6.7.6.1 Vessel working Pressure- 2.0 kg/ cm^2/ F.V 6.7.6.2 Vessel design Pressure – 7 kg/ cm^2 6.7.6.3 Vessel sterilization Temperature- 121 °C 6.7.6.4 Vessel design Temperature- 134 °C	
6.8.Spares and consumables	
Vendor should provide all critical spares such as (not limited to) gaskets, 'O'rings required for minimum two years of operation.	
7.0..CONSTRAINTS	
7.1 Equipment Location and Available Space	
NA	
7.2 Available Utility	
NA	

8.0 ABBREVIATION

Abbreviation	Definition
IVC	Integrated Vaccine Complex
PRV	Pressure Vessel
CIP	Clean In Place
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
HBL	HLL Biotech Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization

9.0 REVISION INDEX

Revision	Date	Reason for Revision
00	24-04-2014	First Draft for Client's Review
01	10-06-2014	As per client mail dated 19-05-2014
02	04-07-2014	Updated as per MoM dated 04-07-2014

URS Annexure 1: List of preferred make of components

S No.	Description	Preferred Make
1.	Pressure gauges	WIKA/Denver/Negele
2.	Safety relief valve	Spirax/Leser/ARI Armaturen