# User Requirement Specifications
# Pressure vessel

| Process Code | Area | Equipment code | Qty(Nos) | Capacity |
|---|---|---|---|---|
| M | Meat digestion area | M-PRV 01 | 1 | 200 L(W.V) |

### URS Annexure List

| URS Annex No. | Detail |
|---|---|
| 1 | Layout showing location of the Pressure vessel in the Meat Media Digestion Block |
| 2 | P&ID as separate annexure |
| 3 | List of preferred MAKE of components |

## Table of Contents

| nne pharmaplan | User Requirement Specifications | | | |
|---|---|---|---|---|
| | **Equipment/System** | Pressure Vessel | | |
| | **Identification** | M-PRV 01 | **Document** | URS/M/PRV 01 |
| | **Effective Date** | 2014-07-07 | **Revision** | 05 |

## 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.

| **Prepared by** | | |
|---|---|---|
| **Name/ Designation** | **Signature** | **Date** |
| **Ms. Shilpa Rao**<br>**Sr. Project Engineer-Biotech**<br>**NNE Pharmaplan India Ltd.** | | |

| **Checked by** | | |
|---|---|---|
| **Name/ Designation** | **Signature** | **Date** |
| **Ms Bincy Joseph**<br>**Assistant Manager**<br>**NNE Pharmaplan India Ltd.** | | |

| **Approved by** | | |
|---|---|---|
| **Name/ Designation** | **Signature** | **Date** |
| **Mr. Vikas Katial**<br>**GM and Head-COC Vaccines**<br>**NNE Pharmaplan India Ltd.** | | |
| **HLL Lifecare Limited** | | |
| **Pasteur Institute of India** | | |

| **Authorized by** | | |
|---|---|---|
| **Name/ Designation** | **Signature** | **Date** |
| **Project Authority**<br>**Pasteur Institute of India** | | |

## 2.0 EQUIPMENT DESCRIPTION

The Pressure vessel with 200 L working volume shall be cylindrical having Torispherical top and bottom dish and shall be provided with tank bottom valve for discharge. The vessel shall be mounted on stainless steel pipe legs and castor wheels. This Pressure vessel shall be used to hold and transfer the meat media. The Mobile Pressure vessel shall be CIP able using the recirculation pump on the meat digestion vessel

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.

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

### 2.0.1 TABLE 1

| S. No. | Description | Purpose | MOC |
|---|---|---|---|
| 1. | Shell | Cylindrical to hold the product | SS316L |
| 2. | Top closure | Torispherical dish | SS316L |
| 3. | Bottom closure | Torispherical dish | SS316L |
| 4. | Insulation | To avoid heat loss | Mineral wool |
| 5. | Cladding | To cover the insulation and to avoid the heat dissipation onto outer surface of the vessel | SS304 |
| 6. | Height/Diameter Ratio | 1.2:1 (vendor to specify ,if there is a change) | - |

### 2.0.2 TABLE 2

| SI.NO | Description | Specification |
|---|---|---|
| 1. | Geometric volume | 250L |
| 2. | Maximum working volume | 200 L |
| 3. | Quantity | 1 No |
| 4. | Surface Finish | Internally Electro polished up to Ra ≤0.8microns(mirror finish) (All Valves Mechanically polished upto Ra ≤0.8microns) |
| | | Internal finish of the interconnecting piping: Ra < 0.8 µm |
| | | Externally Mechanically polished up to Ra≤1.2 microns(matte finish) |

### 2.0.3 General vessel specifications:

a) **Port for Meat media addition:** Port for addition of meat media solution.

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

- Diaphragm Pressure gauge

d) **Air inlet/Exhaust filter:** Pressure vessel vent line includes

- A sterile vent filter (0.2/0.22 micron) with SS housing & a manual diaphragm valve.
- Air PRV

e) **Tank Bottom Valve:** It is also Zero Dead Leg type valve -2 way valve, having a diaphragm.

f) **CIP (Cleaning– In – Place)**: The vessel should have a provision CIP

- SS 316L 360º C Spray ball (fixed type) 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.

**2.0.4 Nozzle schedule**

**1. Top dish:**

- Light/sight glass-1 No
- Spray ball-1 No
- Port for pressure guage-1 no
- TC Spare port-1 No
- Inlet/Exhaust port with sterile filter(1 R 6" 0.2µm PTFE)-1 no

**2. Upper wall side:**

- Port for meat media inlet-1 No
- Vertical view glass (with level marking)-1 No

**3. Bottom dish:**

- Tank bottom valve-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

| nne pharmaplan | User Requirement Specifications | | | | |
|---|---|---|---|---|---|
| | **Equipment/System** | Pressure Vessel | | | |
| | **Identification** | M-PRV 01 | **Document** | URS/M/PRV 01 | |
| | **Effective Date** | 2014-07-07 | **Revision** | 05 | |

**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 costs for necessary options become 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 vendors' 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<br>a. If no comments against any specification shall be considered as "NO" and<br>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/110831/EQP/IRS 01 |
| 12. | Refer tender document NPI/110831/EQP/TED/07 |

| Specifications | | Remarks |
|---|---|---|
| **3.0** | **PROCESS DESCRIPTION** | |
| **3.1** | **Input & Charging method** | |
| 3.1.1 | The Meat media from meat digestion vessel shall be charged into the Mobile pressure vessel | |
| **3.2** | **Brief Process Steps** | |
| 3.2.1 | The meat media will be held in the pressure vessel before it is transferred next process step. | |
| **3.3** | **Output & Discharging method** | |
| 3.3.1 | The meat media is transferred through the bottom valve of the pressure vessel into the next step using pressure. | |
| **4.0** | **PRODUCTIVITY REQUIREMENT** | |
| **4.1** | **Desired/ suggested capacity** | |
| | 250 L Geometric Volume | |
| **4.2** | **Standard batch size** | |
| | 200 L working volume | |
| **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 | |
| **6.3** | **In – Process control** | |
| | Not Applicable | |
| **6.4** | **Level of instrumentation** | |
| | Sufficient and suitable instrumentation for the process, safety and productivity as indicated in the following table: | |

nne pharmaplan®

### User Requirement Specifications

| | | | |
|---|---|---|---|
| **Equipment/System** | Pressure Vessel | | |
| **Identification** | M-PRV 01 | **Document** | URS/M/PRV 01 |
| **Effective Date** | 2014-07-07 | **Revision** | 05 |

| Specifications | Remarks |
|---|---|

| Parameter | Purpose | Type of control and Instrumentation |
|---|---|---|
| Pressure | To monitor the pressure of the vessel during process and SIP | Diaphragm Pressure gauge |

**6.5 Batch data display and record printing**

Not Applicable

**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 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 to ASME BPE compliant

6.7.3 The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment

6.7.4 From user point to the equipment, food grade SIPable flexible hose (3m, 2 Nos) with TC end to be provided.

6.7.5 From the equipment to the drain, food grade SIPable flexible hose with TC end of minimum 3 m length to be provided- 2 nos

6.7.6 Vessel shall be on 3 legs MOC: SS 304 with anti-static double-roll lockable castor wheels for easy transportation.

6.7.7 **Design Parameters:**

6.7.8.1 Shell operating Pressure- FV to 2.0 bar(g)
6.7.8.2 Shell operating Temperature- 20-134°C
6.7.8.3 Shell sterilization Temperature- 121°C
6.7.8.4 Shell design Pressure- Vendor to specify
6.7.8.5 Shell design Temperature- Vendor to specify

## 7.0 CONSTRAINTS

### 7.1 Equipment location and available space

This equipment shall be installed in the Diphtheria & Pertussis block of **Revival of DPT vaccine manufacturing facility** at PII, Coonoor as follows:

**Floor:** Ground floor
**Room size:** 3055(L) X 2450(W) mm
**False ceiling height:** 3 m
**Physical condition of the Meat Digestion room (B1G091) :**

1. Room will be Non-BSL
2. **Class:** EU Class "D"
3. **Differential Pressure:** 10 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 **Annex 1.**

### 7.2 Avaialble Utility

7.2.1. Pure steam @2.4 bar (g) and 121$^0$C-130$^0$C----------(Report requirement)

7.2.2. Compressed air @ 6.0– 8.0 bar (g) ----------(Report requirement)

7.2.3. Electricity:1.5 kW ----------(Report requirement)

## 8.0 ABBREVIATION

| Abbreviation | Definition |
|---|---|
| PII | Pasteur Institute Of India |
| PRV | Pressure Vessel |
| CIP | Clean In Place |
| SIP | Sterilization In Place |
| cGMP | current Good Manufacturing Practices |
| HLL | HLL Life care Limited |
| NPI | NNE Pharmaplan India Ltd |
| ISO | International Standards Organization |

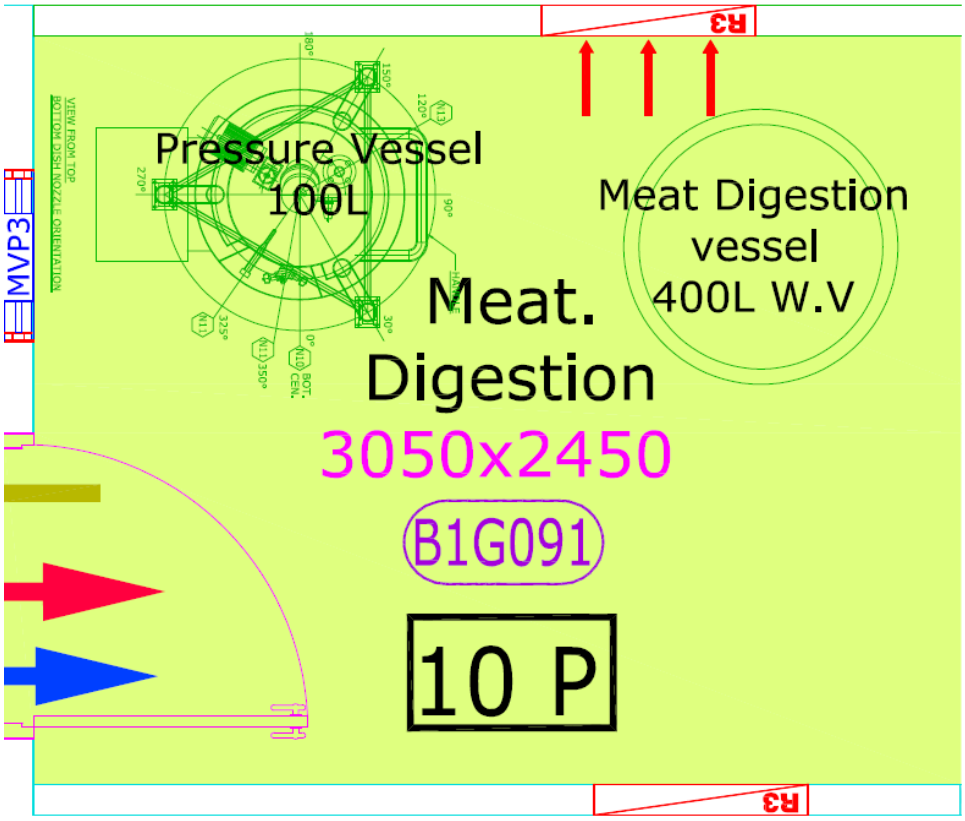
| nne pharmaplan | User Requirement Specifications | | | |
|---|---|---|---|---|
| | **Equipment/System** | Pressure Vessel | | |
| | **Identification** | M-PRV 01 | **Document** | URS/M/PRV 01 |
| | **Effective Date** | 2014-07-07 | **Revision** | 05 |

**REVISION INDEX**

| Revision | Date | Reason for Revision |
|---|---|---|
| 00 | 2012-06-26 | First Draft for Client's Review |
| 01 | 2012-12-10 | Format changed as per HLL requirement |
| 02 | 2013-06-19 | As per the MOM dated 2013-05-28 & 2013-05-29 |
| 03 | 2013-09-26 | As per the discussion with HLL on Video Con on 2013-09-11 ,2013-09-12 and comments received on 2013-09-20 |
| 04 | 2014-01-22 | Revised as per commented URS received on 2014.01.17 |
| 05 | 2014-07-07 | Revised as per the discussion with HLL on 2014-06-19 and 2014-06-20 |

**Annexure 1: LAYOUT**

**Room No: B1G091**



**URS Annexure 3: List of preferred make of components**

| | | |
|---|---|---|
| | **MECHANICAL** | |
| 1. | Pressure gauges | WIKA/Denver/Negele |
| 2. | Air filter cartridge | Sartorius/PALL / Millipore |
| 3. | Spray ball | HAKE |
| 4. | Diaphragm valve(Manual) | GEMU/Burkert/ITT/SED/Saunders |
| 5. | Ball valve(Manual) | Modentic/Saunders/Alfa laval |
| 6. | Air-PRV | Festo/SMC |
| 7. | Rupture disc | Zook/Elfab/FIKE |