User Requirement Specifications
Meat Digestion vessel

Process Code	Area	Equipment code	Qty(Nos)	Capacity
M	Meat Digestion Vessel	M-MDV 01	1	500 L (G.V)

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Meat Digestion Vessel in the Meat media preparation block
2	P&ID as separate URS annexure
3	List of preferred MAKE of components

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	Identification	M-MDV 01	**Document**	URS/M-MDV 01
	Effective Date	2014-10-16	**Revision**	09

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 **Sr. Project Engineer-Biotech** **NNE Pharmaplan India Ltd.**		

Checked by		
Name/ Designation	**Signature**	**Date**
Ms. Bincy Joseph /Mr. K. Sridhar Babu **Assistant Manager- Validation & GMP Compliance** **NNE Pharmaplan India Ltd.**		

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

Authorized by		
Name/ Designation	**Signature**	**Date**
Project Authority **Pasteur Institute of India**		

2.0 EQUIPMENT DESCRIPTION

The meat digestion vessel is used for the meat media preparation which is required for Diphtheria bulk production. Design, function and control of the unit have to be cGMP compliant.

The general design must be hygienic, with no dead legs and no air pockets. The system must be fully drainable. The vessel should be of fixed type mounted on legs with pad plate.

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

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

S. No.	Description	Purpose	MOC	Vendor remarks
1	Shell	To hold and digest the media for preparation	SS316L	
2	Top closure	Torispherical dish	SS316L	
3	Bottom closure	Torispherical dish	SS316L	
4	Jacket	Spiral	SS304	
5	Insulation	To avoid heat loss	Mineral wool	
6	Cladding	To avoid the heat dissipation onto the outer surface of the vessel	SS304	
7	Agitator	Top driven agitator with single dry mechanical seal with anchor blade. VFD to be provided to control RPM of agitator	-	
8	Height/Diameter Ratio	1:1.5	-	

2.0.2. TABLE 2

SI.NO	Description	Specification	Vendor Remarks
	Geometric volume	500L	
	Maximum working volume	400L	
	Quantity	1 No	
	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)	

Description	Vendor Remarks
2.0.3. General Requirements:	
a. **Addition of meat:** 750mm dia -Manhole on the lid shall be provided for minced meat addition and skimming the fat mass manually using SS mesh from the media.	
b. **Port for addition of enzyme solution:** Enzyme solution shall be added into the vessel	
c. **Port for acid or alkali addition:** Acid and Alkali shall be added manually.	
d. **Spray ball:** 2 Nos removable type spray balls covering the entire area with 360^0 shall be provided on the top dish for the addition of WFI and for CIP solution.	
e. **Agitator:** Top mounted agitator with single dry mechanical seal with anchor blade. It will be used for mixing the liquids of high viscosity. • Bearing frame and direct motor drive arrangement • Shaft seal: Single mechanical dry running seal • Shaft type and length shall be decided by the vendor according to the height of the vessel • Vendor shall specify the following: – Shaft diameter – Width of the blade – Height of the blade – Diameter of the disc – Tip speed – Orientation of Shaft – RPM • MOC: – SS 304 bearing frame – SS 316L shaft of the agitator – SS 316L disc – SS 316L impeller	
f. **Temperature Control:** The temperature during meat digestion shall be controlled via circulation of utilities (plant steam, cooling water, chilled water, etc) in the jacket. Temperature control during meat digestion should be settable [30 DegC to 110 DegC] according to different process sequences with a timer. (tolerance limit: ± 2 ºC) • Bourdon type pressure gauge for jacket • Steam trap to be provided for jacket	
g. **Sampling valve:** It should be flush welded zero dead lag valve without steaming provision.	
h. **Vessel drain Valve:** The drain valve shall be directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be 2 to 2.5 inch butterfly valve / ball valve with TC End • It should have a multi size strainer (Vendor to specify design)	

i. **Controller**- Relay based controller

j. **SS Mesh** (Vendor's scope of supply)- SS316L mesh with a handle

- Diameter of the mesh should be designed so as to fit in through the manhole
- The mesh should be designed to access the entire vessel.

k. **SS Ladder** (Vendor's scope of supply)- SS 304 ladder to access the top of the vessel **.**It can be either integrated with the vessel or separate (Vendor to Specify) .

- Supply of SS Mesh and SS ladder in the scope of vendor

l. **CIP (Cleaning– In – Place)**: The vessel should have a provision cleaning. The cleaning media shall be sent into the vessel, agitated and drained (once through)

SS 316L 360º C Spray ball (Removable 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

The top dish will have:

- Manhole 750mm- 1 no
- Sight /Light port (preferably metal fused type)- 1 no
- Port for agitator
- Spray balls (Removable Type)- 2 nos
- TC Spare port (1.5inch TC end) - 1 no

2. Upper wall side

- Port for enzyme addition- 1 no 1.5inch TC end
- Port for Acid addition and Alkali addition- 1 inch- 1 no
- Vertical view glass(with level marking)- 1 no
- Jacket outlet- 1 no

3. Lower wall side

- Sampling Port
- Port for temperature sensor- 1 no
- Jacket inlet-1 no

4. Bottom dish

- Port for Vessel drain 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

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Equipment/System	Meat Digestion Vessel		
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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 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 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 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_110831_IRS_PII_01
12.	Refer the tender document :NPI/110831/EQP/TD/07

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Equipment/System	Meat Digestion Vessel		
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Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 **Input & Charging method**	
3.1.1 The vessel shall be prepared for use after performing once through wash	
3.1.2 The WFI at 80^0C-85^0C shall be added into the vessel.	
3.1.3 The temperature shall be brought down to 35^0C via circulation of utilities (cooling water, chilled water, etc.) in the jacket	
3.1.4 Minced meat is charged into the vessel	
3.1.5 Enzyme solution is added, which helps to digest the minced meat particles.	
3.1.6 Removal of fat manually with SS mesh according to SOP	
3.1.7 Temperature is raised to 50^0C ± 2^0C and further it is taken upto 100^0C for about 10 minute via circulation of utilities (Plant steam) in the jacket.	
3.2 **Brief Process Steps**	
3.2.1 Vigorous agitation of the product.	
3.2.2 The temperature to be maintained initially is 50^0C and later at 100^0C by charging Plant steam through the jacket and pH shall be adjusted to 7 initially and after digestion pH of 4.1-4.2 to be maintained by the addition of acid/alkali. All pH adjustments are manual.	
3.3 **Output & Discharging method**	
3.3.1 The digested meat medium is taken out through the vessel drain valve for filtration.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 **Desired/ suggested capacity**	
500 L Geometric volume	
4.2 **Standard batch size**	
400 L Working volume	
4.3 **Change Over Time**	
Not Applicable	
4.4 **Others(If any)**	
Not Applicable	
5.0 CONTAINMENT	
Not Applicable	

Specifications	Remarks
6.0 GMP REQUIREMENTS	
6.1 **Process control**	
The equipment must operate and control the following process parameters:	
6.1.1 Temperature during meat digestion.	
6.1.2 Temperature of the jacket (only indication not control)	
6.1.3 Adjustable agitation 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:	
6.2.1. Abrupt product temperature	
6.2.2. Agitator speed out of range	
6.3 **In – Process control**	
6.3.1 Should have provision for sampling of product solution.	
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 meat digestion temperature	Temperature sensor
Temperature	To monitor, indicate jacket temperature	Temperature sensor
Speed	To control the agitator speed	Variable frequency drive with indicator

6.5 **Batch data display and record printing**	
Batch data to be printed by using real time printer and trends to be printed in strip chart recorder.	
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. All nozzle connection should comply with dead leg requirement.	
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	

Specifications	Remarks
sterilization	
6.6.4. Utility operation shall be preferably automatic and valves shall be placed inside of aseptic area.	
6.6.5. Isolation valves should be provided wherever necessary	
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 Total motor drive assembly with SS304 cover	
6.7.4 Vendor Shall provide FRL's (Filters, Regulators, Lubricators)	
6.7.5 **Design Parameters:** 6.7.5.1 Shell working Pressure- FV to 2.5 bar(g) 6.7.5.2 Shell working Temperature- 20-134°C 6.7.5.3 Shell sterilization Temperature- 121°C 6.7.5.4 Shell design Pressure- Vendor to specify 6.7.5.5 Shell design Temperature- Vendor to specify 6.7.5.6 Jacket working Pressure- FV to 4 bar(g) 6.7.5.7 Jacket working Temperature- 135°C 6.7.5.8 Jacket design Pressure- Vendor to specify 6.7.5.9 Jacket design temperature-Vendor to specify	
6.7.6 From user point to the equipment, food grade SIPable flexible hose (3 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 3m length to be provided- 3 nos	
6.7.8 Non sterile flexible hoses for black utility to be part of equipment supply (Vendor to specify quantity)	
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: Fixed type	
6.7.11 Distance piece for SS mesh to be provided	
6.7.12 **Performance criteria during FAT/SAT:** a. Spray ball coverage test during FAT b. Thermal mapping c. All FAT/SAT IQ,OQ as per IRS	

Specifications	Remarks
7.0 CONSTRAINTS	
7.1 **Equipment location and available space**	
This equipment will be installed in the Meat media preparation block of the DPT vaccine manufacturing facility at PII, Coonoor as follows:- **Floor:** Ground; **Room No:**B1G091 **Plant:** Meat media preparation **Room dimension :** 3.25 m x 2.45 m **False ceiling height**:3 m **Physical condition of the room:** 1. Room will be NON-BSL 2 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 **URS Annex 1.**	
7.2 **Available Utility**	
7.2.1 Cooling Water @3 bar _____ (Report requirement)	
7.2.2 Purified water @2.5 bar(g)_____ (Report requirement)	
7.2.3 Compressed Air @8-10 bar(g)_____ (Report requirement)	
7.2.4 WFI (Hot loop)@3 bar(g) _____ (Report requirement)	
7.2.5 Plant Steam@3-8 bar(g) _____ (Report requirement)	
7.2.6 Electricity : 2 kW (Report requirement)	
8.0 ABBREVIATION	

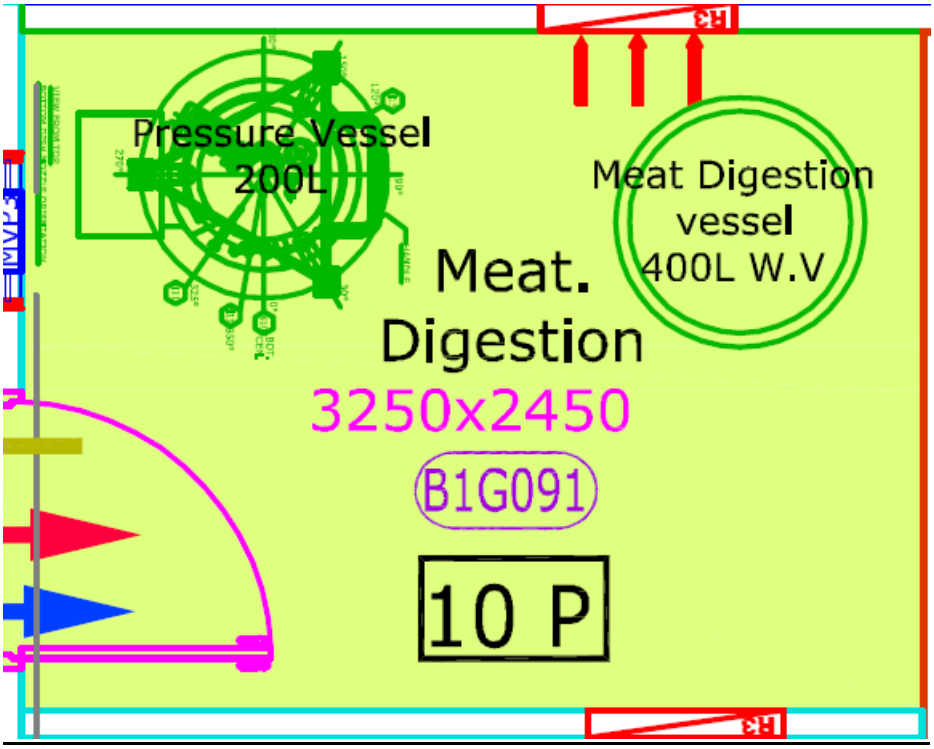
Abbreviation	Definition
PII	Pasteur Institute Of India
MDV	Meat Digestion Vessel
cGMP	current Good Manufacturing Practices
HLL	HLL Lifecare Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization

Abbreviation	Definition
EUGMP	European Union Good Manufacturing Practices
UPS	Un-interrupted Power Supply
HEPA	High Efficiency Particulate Air

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	2013-06-26	As per the discussion with HLL/PIIC on 2013-05-28 and 2013-05-29 and Internal review
03	2013-09-24	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 2013-11-12 and Telecon on 2013-11-15
06	2014-01-02	Revised as per the discussion with HLL on Video Con on 2014-01-02
07	2013-10-28	Revised as per comments received on URS by email on 2014-01-20
08	2014-07-01	Revised as per the discussion with HLL on 2014-06-19 and 2014-06-20
09	2014-10-16	Revised as per the discussion with HLL on 2014-10-16

URS Annexure 1: LAYOUT: Room No:B1G091



URS Annexure 3: List of preferred make of components

	INSTRUMENTATION	
1.	Temperature transmitter	RADIX/ YOKOGAWA/EMERSON/WIKA
2.	Temperature sensor	NEGELE/ RADIX
3.	Pressure regulator	FESTO
	MECHANICAL	
4.	Pressure gauges	WIKA/DENVER/NEGELE
5.	Spray ball	HAKE
6.	Diaphragm valve(Manual)	GEMU/ITT/SED/BURKERT/ SAUNDERS
7.	Ball valve(Manual)	MODENTIC/SAUNDERS/ALFA LAVAL
8.	Sampling valve	GEMU/ SAUNDERS /ITT/SED/Burkert
9.	Agitator	INOXPA/IKA/PRG
10.	Flexible hose	AB Synthetic/ AMI Polymer/VENAIR
	PNEUMATIC	
11.	Diaphragm valve(Automatic)	GEMU / ITT/SED/BURKERT/SAUNDERS
12.	Angle seat valve(Automatic)	GEMU / ITT/SED/BURKERT/ SAUNDERS
13.	Air-PRV	Festo/SMC
	ELECTRICAL	
14.	Lamp	PAPENMEIER