User Requirement Specifications
CIP Trolley

Process Code	Area	Equipment code	Qty. (Nos.)	Capacity
P	Pertussis	P- CIP 01	1	-

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the CIP Trolley in the Pertussis 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 Validation and GMP compliance team of "NNE Pharmaplan India for the project "Revival of DPT Vaccine 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 and authorized by the appropriate Project Authority.

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2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a “CIP Trolley”.

CIP trolley will be used to re-circulate the cleaning media inside the vessel/ closed equipment.

- The skid consists of Centrifugal pump with variable frequency drive, Pneumatic diaphragm valves, Flow Switch, Conductivity sensor (0 to 200 μS/cm), interconnecting SS pipes and flexible hoses for connection between the inlet/ outlet of vessel.
- The assembly is mounted on a SS skid with lockable castor wheels with anti-static property.

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 on 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.
IV.	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.
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 Specification and Specific Instructions with URS; NPI_110831_IRS_PIIC_01
XII.	Refer Tender document with URS; NPI/110831/EQP/TD/07

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 INPUT & CHARGING METHOD	
The outlet of the vessel will be connected with the inlet of the pump and inlet spray ball port of the vessel will be connected with the outlet of the pump with the help of flexible hoses.	
3.2 BRIEF PROCESS STEPS	
• The outlet of the vessel will be connected with the inlet of the centrifugal pump. • The pump outlet is connected to the spray ball. • The CIP solution will be charged into the vessel. • The solution will be recirculated with the help of centrifugal pump provided on CIP trolley. • The drain of the trolley will be connected to the room drain and the solution will be drained as per cycle time	
3.3 OUTPUT & DISCHARGING METHOD	
The drain of the trolley will be connected to the room drain and the media will drained as per cycle time.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 DESIRED/ SUGGESTED CAPACITY	
This system will be catering all vessels of capacity 20-500L (G.V)	
4.2 STANDARD BATCH SIZE	
Not Applicable	
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 control the following process cycle:	

Specifications	Remarks
6.1.1 Duration of each cycle.	
6.1.2 Conductivity (0 to 200 µS/cm)	
6.1.3 No flow - cut–off of pump	
6.2 FAILURE MODE DETECTION	
6.2.1 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
a) Emergency stop activated	
b) Power	
6.2.2 Following condition need only notification to operator for procedural control	
a) End of any/all process sequence.	
6.3 IN –PROCESS CONTROL	
Not Applicable	
6.4 LEVEL OF INSTRUMENTATION	

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Instrumentation
Flow	To check flow	Flow switch
Speed	To control the speed	Variable Frequency Drive (VFD)
Conductivity	CIP Recirculation / Drain Line Conductivity	Conductivity monitor / indicator

6.5 BATCH DATA DISPLAY AND RECORD PRINTING	
6.5.1 Refer IRS(Installation requirement Specification and Specific Instructions)	
6.5.2 Non editable data shall be available / transferred to USB Drive for printing the batch report, alarm log	
6.5.3 HMI should be provided	
6.6 GMP REQUIREMENTS (OTHERS)	
6.6.1 All valve, flexible pipe connections and joints should be sanitary type (preferably tri-clover connection).	

	Specifications	Remarks
6.7	SPECIFIC REQUIREMENTS	
6.7.1	All attachments required for fixing nozzles, supply pipes and return pipes should be provided by vendor only	
6.7.2	All the operations should be automatic through control panel, without any manual interventions using pneumatic actuated diaphragm valves.	
6.7.3	All the flexible piping used for cleaning services should be of SS re-enforced and PTFE lined to withstand pressure, temperature.	
6.7.4	Solvent may be used for cleaning hence all electrical connection /accessories should be flame proof.	
6.7.5	The pump should have a VFD.	
6.7.6	Cables, air tubes and regulators etc. required from the point (single utility point) to equipment is in scope of vendor	
6.7.7	Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software, if used to generate, process, store the quality critical data must be validated and must comply 21 CFR Part 11 requirements	
6.7.8	**Pump specification:** **Flow rate:** 6-8 m^3/ h **(Vendor to specify)** **Operating temperature:** 80-90°C **MOC:** SS304 **Seal:** FDA approved	
6.7.9	Vendor shall provide the FRL (Filter, regulator, lubricator), automatic valve assembly and air pressure switch for instrument air. Connections to automatic diaphragm valve shall be in vendor scope.	
6.7.10	From user point to the equipment, food grade SIPable flexible hose (2 m, 2 nos) with 1 inch TC end should be provided for all vessels.	
6.7.11	From the equipment to the drain, food grade SIPable flexible hose (2 m, 2 nos) with 1 inch TC end should be provided for all vessels.	
7.0	**CONSTRAINTS**	
7.1	EQUIPMENT LOCATION AND AVAILABLE SPACE	
	This equipment will be installed in the Pertussis block of Revival of DPT vaccine manufacturing facility at PII, Coonoor as follows:	

For P-CIT 01

Media and Buffer Room (B1G028)

1. Room will be non-BSL
2. Class: EU Class "C" for B1G028
3. Differential Pressure: 25 Pa Absolute for B1G028
4. Temperature maintained: 22°C ±2°C
   Relative Humidity: <60% RH

7.2 AVAILABLE UTILITY

- Electricity: _____(Report Requirement)
- Compressed air _____(Report Requirement)

8.0 ABBREVIATION

List of abbreviations

Abbreviation	Definition
µS/cm	Micro Siemens per centimeter
CFR	Code of Federal Regulation
NPI	NNE Pharmaplan India
PIIC	Pasture Institute of India, Coonoor
QA	Quality Assurance
SS	Stainless steel
URS	Users requirement specification
WHO	World Health Organization

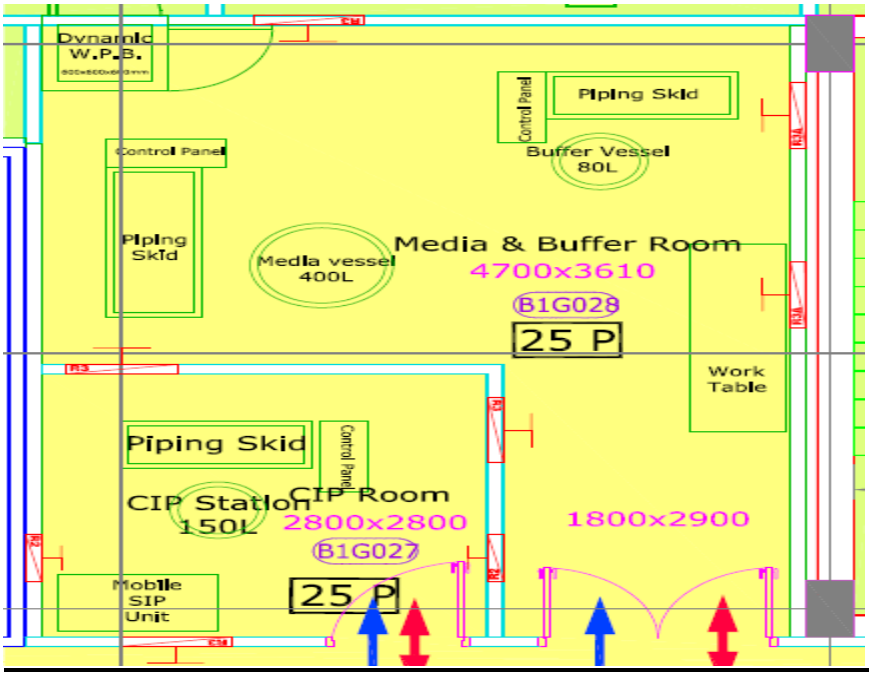
9.0 REVISION INDEX

Revision	Date	Reason for revision
00	2014-10-17	First Draft for Client's Review

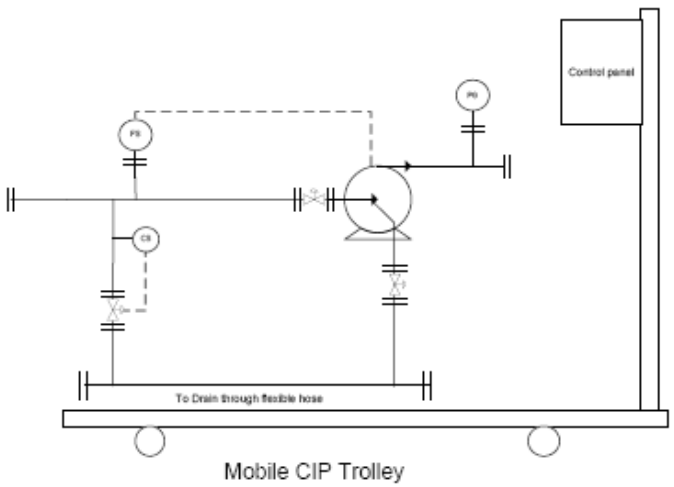
URS Annexure 1: LAYOUT POSITION

For P-CIT 01

Room No. : Media & buffer room (B1G028)



URS Annexure 2: CIP trolley schematic



Mobile CIP Trolley

URS Annexure 3: List of preferred make of components

SI.NO	COMPONENTS	MAKE
1.	PLC , HMI	Siemens/ Alan Bradley
	MECHANICAL	
2.	Pressure gauge	WIKA/Denver/Negele
3.	Diaphragm valve(Manual)	GEMU/Burkert/ITT/SED/saunders
4.	Conductivity sensor	Mettler Toledo/ E&H /Yokogawa
5.	Ball valve(Manual)	Modentic/Saunders/Alfa laval
6.	Centrifugal pump	Alfa Laval/ Grundfos
7.	Flexible hose	AB Synthetic/ AMI Polymer/Venair
	PNEUMATIC	
8.	Diaphragm valve(Automatic)	GEMU/Burkert/ITT/SED/saunders
9.	Angle seat valve(Automatic)	GEMU/Burkert/ITT/SED/saunders