User Requirement Specifications
Mobile CIP Trolley

Block Code	Area	Identification #	Qty (Nos)	Capacity(WV)
R1	Measles and Rubella Bulk Block	R1-CIT-01	1	NA

URS Annexure List

URS Annex No.	Detail
1	Mobile CIP trolley Schematic
2	List of preferred MAKE of components
3	Location of the equipment in the Layout

Table of Contents

1.0 APPROVAL SIGNATURE

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 should 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			
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HLL Biotech Limited			
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2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a "Mobile CIP Trolley".

Mobile CIP trolley will be used to prepare the cleaning Solution, re-circulate the cleaning solution inside the vessel/ closed equipment.

- The skid consists of Centrifugal pump with variable frequency drive, Acid / Alkali dosing pumps, Heat exchanger, Pneumatic diaphragm valves, Flow Switch, Conductivity sensors, 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. 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.
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 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 vendors' 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 should be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it should 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 HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01

XII.	Refer Tender document with URS; NPI_120310_EQP_S1_TD_16

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 INPUT & CHARGING METHOD	
The outlet of the vessel will be connected with the inlet of the re-circulation pump and inlet of the spray ball port of the vessel will be connected with the outlet of the mobile CIP trolley with the help of flexible hoses.	
3.2 BRIEF PROCESS STEPS	
• Vessel will be connected with the mobile CIP trolley • Mobile CIP system will perform all the sequence i.e., Preparation, Transfer, Once through, Recirculation etc. from the system itself by taking the IO from victim Vessel PLC. The system should be capable of the following sequence of cleaning cycle: 1) <u>Wash Phases:</u> Once through with PW rinse- 55-60°C 2) <u>Alkali addition through metering/dosing pump:</u> PW addition through level sensor set point Re-circulation with Alkali solution- 55-60 °C 3) <u>Intermediate wash:</u> Re-circulation with PW - 55-60 °C 4) <u>Acid addition through metering /Dosing pump</u>: PW addition through Level sensor set point Re-circulation with Acid solution - 55-60 °C Re-circulation with PW - 55-60 °C 4) <u>Rinse Phases:</u> Recirculation/Once-through with WFI 5) <u>Drying</u>: Air blow to the equipment • Cleaning solution (acid / Alkali) will be prepared in process tank and re-circulated within the tank by using re-circulation pump and heated using heat exchanger. • The purified water & WFI required for final rinse will be directly taken from the loop. • **<u>Note:</u>** CIP solution preparation in the respective vessel is based on conductivity set point, a feedback signal from conductivity sensor in the recirculation line of the pump is employed for controlled acid/alkali dosing.	

Specifications	Remarks
3.3 OUTPUT & DISCHARGING METHOD	
The drain of the trolley will be connected to the room drain and the solution will drained as per cycle time.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 DESIRED/ SUGGESTED CAPACITY	
Cleaning capacity of the vessels shall be of 100 – 200 L	
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:	
6.1.1 Duration of each cycle.	
6.1.2 Number of cycles.	
6.1.3 Quantities of wash liquid in each cycle.	
6.1.4 Temperature of washing liquid.	
6.1.5 Conductivity	
6.1.6 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	

Specifications	Remarks
b) Power	
6.2.2 Following condition need only notification to operator for procedural control	
a) End of any/all process sequence.	
b) Low compressed air pressure	
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 avoid dry run of pump	Flow switch
Temperature	To monitor , control and record the temperature	Temperature sensor and transmitter
Speed	To control the pump speed	Variable Frequency Drive (VFD)
Conductivity	To monitor, control and record the Conductivity	Conductivity sensor with transmitter in re-circulation line
Conductivity	To monitor and record the Conductivity	Conductivity sensor with transmitter in drain line

6.5 BATCH DATA DISPLAY AND RECORD PRINTING	
6.5.1 The system should be provided with all necessary automation and instrumentation for establishing interface (Handshake b/w the Mobile CIP trolley & Process tank) with other systems i.e., Media prep. Vessel	
6.5.2 Non editable data shall be available / transferred to USB Drive for printing the batch report, alarm log	
6.5.3 The HMI should be of touch screen type (Provision for manual operation to be provided). All settings should be user adjustable. HMI and Control Panel should be mounted on mobile skid. • Human machine interface must be used to enter the process details, which should appear in the print out. • All critical alarms, Critical parameters and interlocks • All Recipes/ sequences • P&ID of the system along with instrumentation details	

Specifications	Remarks
• Login details • HMI screen showing simulation of valves	
6.6 GMP REQUIREMENTS (OTHERS)	
6.6.1 All valve, flexible pipe connections and joints should be sanitary type (preferably tri-clover connection).	
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 Dedicated dosing pumps to be considered for dosing the required amount of Acid & Alkali solution	
6.7.3 Non-return valves shall be provided for Acid/Alkali dosing lines.	
6.7.4 All the operations should be automatic through control panel, without any manual interventions using pneumatic actuated diaphragm valves.	
6.7.5 All the flexible piping used for cleaning services should be of SS re-enforced and PTFE lined to withstand pressure, temperature.	
6.7.6 Solvent may be used for cleaning hence all electrical connection /accessories should be flame proof.	
6.7.7 The pump should have a VFD.	
6.7.8 Cables, air tubes and regulators etc. required from the point (single utility point) to equipment is in scope of vendor	
6.7.9 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	
6.7.10 **Pump specification:** **Flow rate:** 6-8 m^3/ h **(Vendor to confirm)** **Operating temperature:** 80-90°C **MOC:** SS316L **Seal:** FDA approved	
6.7.11 From user point to the equipment, food grade SIPable flexible hose (2 m, 2 nos) with 1 inch TC end should be provided for the vessel.	
6.7.12 From the equipment to the drain, food grade SIPable flexible hose (3 m, 2 nos) with 1 inch TC end should be provided for the vessel.	

7.0 CONSTRAINTS

7.1 EQUIPMENT LOCATION AND AVAILABLE SPACE

This equipment will be installed in the **Measles and Rubella Bulk Block** of IVC Vaccines manufacturing facility at HLL BIOTECH LIMITED, Chengalpattu:

Floor: Ground floor
Room Area : 27 m^2
False ceiling height: 3000 mm

Physical condition of the room:

1. Class: EU Class "C"
2. Differential Pressure: 50 Pa
3. Temperature maintained: 22±2 °C
4. Relative Humidity: < 55% RH

7.2 AVAILABLE UTILITY

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

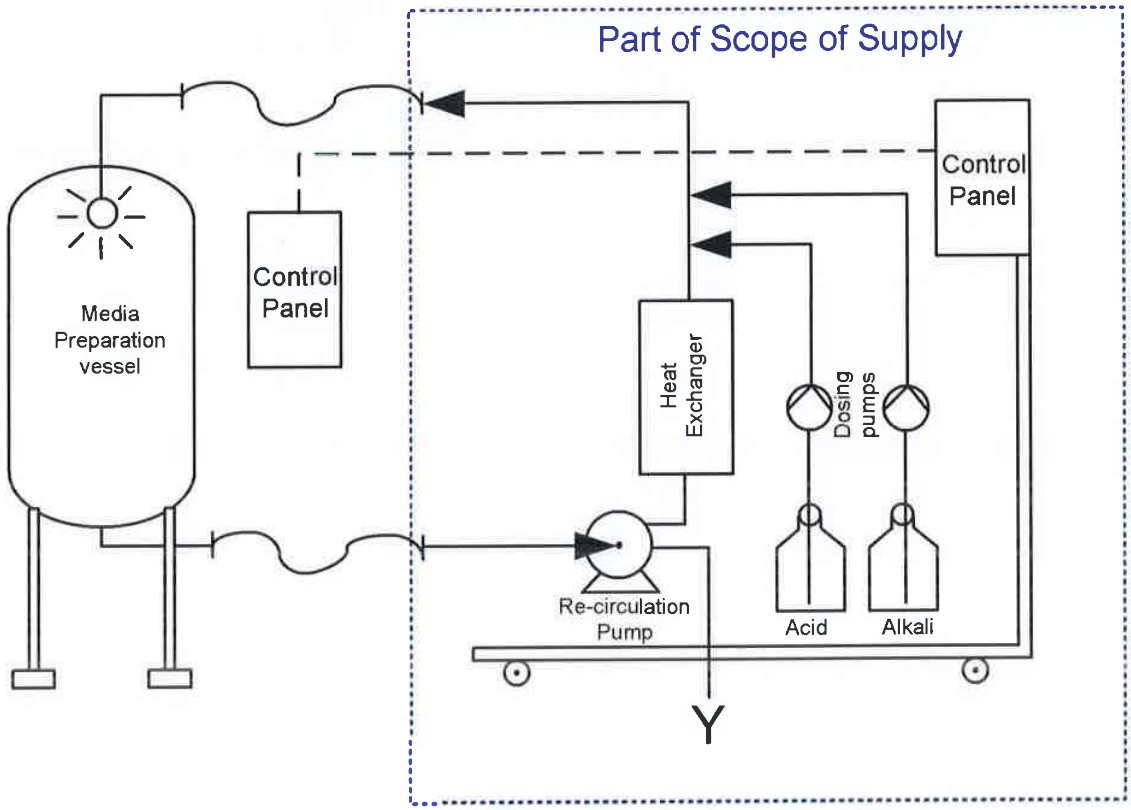
8.0 ABBREVIATION

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

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	11-04-2016	First Draft for Client's Review

URS Annexure 1: Mobile CIP trolley schematic



URS Annexure 2: List of preferred make of components

S NO	COMPONENTS	MAKE
1.	Control Panel	Siemens/ Alan Bradley
2.	Temperature transmitter	Radix/ Yokogawa/Emerson
	MECHANICAL	
3.	Pressure gauge	WIKA/Denver/Negele
4.	Diaphragm valve(Manual)	GEMU/Burkert
5.	Conductivity sensor	Mettler Toledo/ E&H /Yokogawa
6.	Ball valve(Manual)	Modentic / Alfa laval / Gemu
7.	Centrifugal pump	Masterflex / Alfa Laval/ Grundfos
8.	Flexible hose	Saint Gobian / BBS / Venair
	PNEUMATIC	
9.	Diaphragm valve(Automatic)	GEMU / Burkert / Saunders
10.	Angle seat valve(Automatic)	GEMU / Burkert / Saunders

URS Annexure 3: Location of the equipment in the layout
Room No: R1G034
Room name: Media prep.