User Requirement Specifications
Mobile CIP Trolley
BF-CIT 01

Revision index

Revision	Date	Reason for revision
00	2013-01-15	First Draft for Client's Review
01	2013-02-12	Changes incorporated as per HLL comments dated 2013-02-12
02	2013-04-15	As per HLL comments by mail dated 2013.04.13 following changes are incorporated 1. Line containing "TC clamp" in the List of MAKE of components is deleted.

URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the installation of the Mobile CIP trolley
2.	Mobile CIP trolley schematic
3.	List of preferred MAKE of components

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1.0 Approval Signature

This document is prepared by the Process and Validation and GMP compliance team of "NNE Pharmaplan India for the project "Revival of BCG Vaccine Laboratory" (**project number:-110729**) of BCG Vaccine Laboratory, Guindy, Chennai 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

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

- The CIP recirculation system consists of a pump skid with a control panel.
- The skid consists centrifugal pump with variable frequency drive for re-circulation of cleaning media, Pneumatic diaphragm valves, pressure gauge, 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.

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 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_110729_IRS_BCG_01
XII.	Refer Tender document with URS; NPI/110729/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.	
• The Acid and alkali solutions shall be prepared in the vessel that are to be CIP'd and then re-circulated using the re-circulation pump in the CIP trolley It has a provision for Conductivity testing using Conductivity sensor for the end point determination of cleaning cycle.	
• Other Cleaning media i.e.; WFI will be charged directly from the utility point.	
3.2 Brief Process Steps	
• The media will be recirculated with the help of centrifugal pump provided on CIP trolley. • The drain header of the trolley will be connected to the room drain and the media will be drained as per cycle time.	
3.3 Output & Discharging method	
The drain header 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 vessels of capacity 40L (G.V)	
4.2 Standard batch size	
Not Applicable	
4.3 Change Over Time	
Not applicable	
4.4 Other Productivity Requirement	
Not applicable	

Specifications	Remarks
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 Pressure	
6.1.3 Conductivity (0 to 200 μS/cm)	
6.1.4 Quantities of wash liquid in each cycle.	
6.1.5 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
Time	Cycle time	Timer
Pressure	To monitor the pressure in the supply line	Pressure gauge
Conductivity	To measure the conductivity of the cycle at the end point	Conductivity monitor / indicator

Specifications			Remarks
Flow	To check flow	Flow switch	

6.5	**Batch data display and record printing**	
	Refer IRS(Installation requirement Specification and Specific Instructions)	
6.6	**GMP requirements (Others)**	
6.6.1	All valve and joints should be sanitary type (preferably tri-clover connection).	
6.6.2	Pressure gauge shall be of sanitary type	
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 smooth bore with re-enforcement to withstand CIP pressure, temperature and shall be compatible to acid and alkali solutions(80ºC)	
6.7.4	All flexible pipe connections should be provided with triclover joints or quick release couplings (just push in/ pull out type) with flow in-built stop valve	
6.7.5	The supply and suction pumps should have capacity for minimum 2 volume changes per hour of the highest volume vessel.	
6.7.6	Vendor should provide the following details in the quotes apart from those mentioned in the URS: (a) Makes of pumps (Supply and suction), Conductivity meter, Valves, Control panel etc. (b) Schematics of the mobile CIP trolley	
6.7.7	Fully automatic Control panel based operation.	
6.7.8	The Vendor shall ensure maintenance parts availability for a minimum of 15 months from delivery.	
6.7.9	Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor	
6.7.10	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	

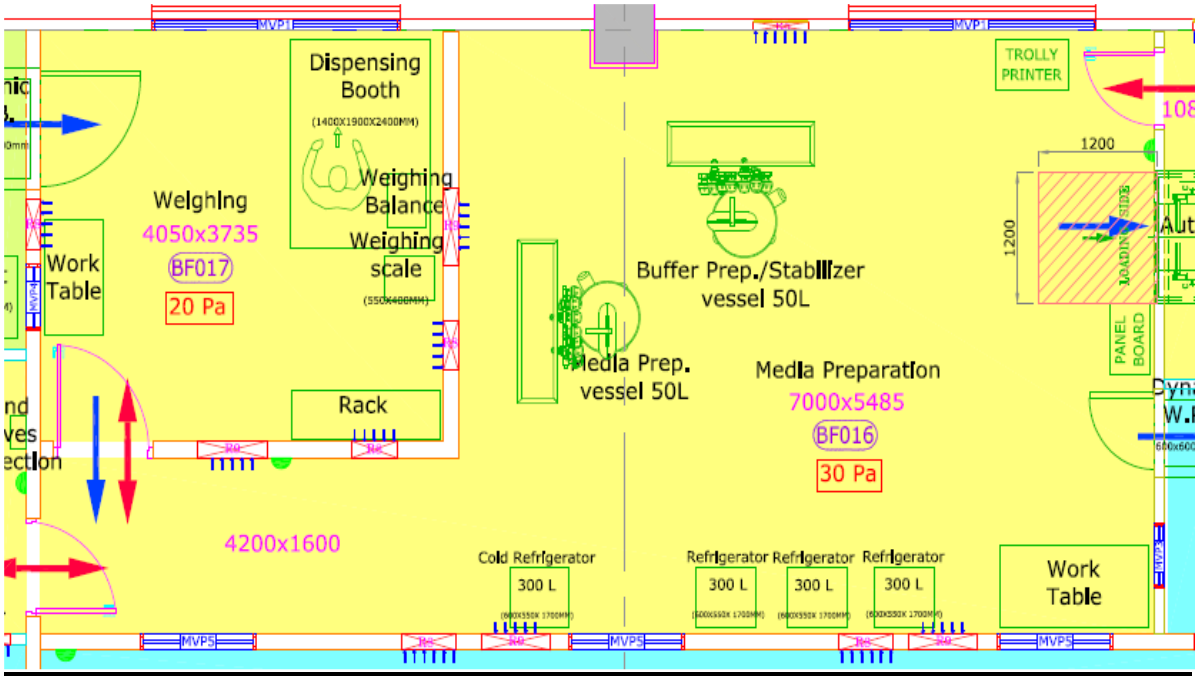
Specifications	Remarks
6.7.11 **Pump specification:** **Flow rate:** 1.5 m^3/ hr **Process Time:** 1-2 hrs **Operating temperature:** 70-80°C **MOC:** SS304 **Seal:** FDA approved	
6.7.12 Vendor shall provide the FRL (Filter, regulator, lubricator), automatic valve assembly and air pressure switch for instrument air. Connections to automatic diaphragm valve shall be in vendor scope.	
6.7.13 Vendor has to design the system based on the desired flow rate for performing the CIP for media & buffer preparation vessels.	
7.0 Constraints	
7.1 Equipment location and available space	
This equipment will be installed in the area as follows. **Equipment Location:** Floor: First floor- Bulk Block Plant: Revival of BCG Vaccine manufacturing laboratory, Guindy The equipment location is indicated in the relevant block of the layout enclosed as URS Annex-1. **Physical condition of the rooms:** **For BF-CIT 01** Media Preparation (BF016) 1. Room will be non-hazardous 2. Class: EU Class "C" 3. Room Dimension: 45.22 m^2 4. Door width: 1000 mm 5. Differential Pressure: 30 Pa Absolute 6. Temperature maintained: 22°C ±1°C 7. Relative Humidity: <55% RH	
7.2 Available utility	
➢ Electricity: 3 kW(Report Requirement) ➢ Compressed air@ 8-10 bar_____(Report Requirement) ➢ WFI@3 bar_____(Report Requirement)	

8.0 Abbreviation

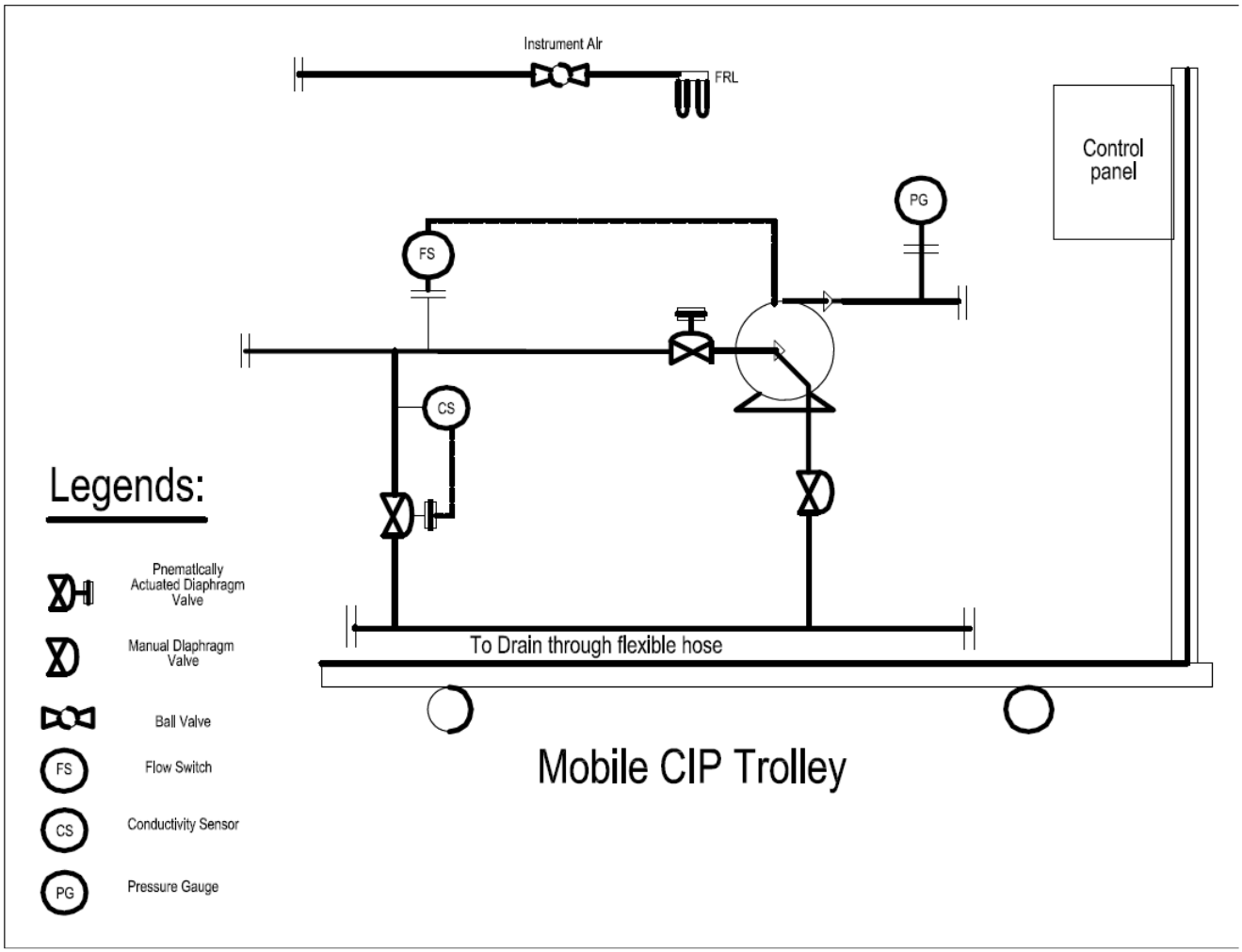
List of abbreviations

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

URS Annexure 1: LAYOUT OF BCG BULK BLOCK
Room No: BF016 (Media Preparation)



URS Annexure 2: Schematic Mobile CIP Trolley



URS Annexure 2: List of Preferred Make of components

S. No	Description	Make
1.	Pressure Regulating valve	Festo/Norgren
2.	Silicon Braided Hose (For CIP IN and Out)	Saint Gobain / Watson Marlow
3.	Solenoid Valve and Coil	FESTO/Norgren/ Patcon
4.	Flow Switch	Soham Automation/KSR Kuebler
5.	Diaphragm Valve, SS 316L	Gemu /Saunders(Crane)/Burkert
6.	Conductivity Sensor	E&H / Hamilton / Mettler
7.	Conductivity indicating Controller cum Transmitter	E&H / Hamilton / Mettler
8.	Centrifugal Pump	Grundfos/Inoxpa/Alfalaval
9.	Diaphragm Pressure Gauge	Siemens/ Wika
10.	Electro Magnetic Dosing Pump	Sandur Fluid Controls/Prominent
11.	Dosing Bottle	Thermo fisher/ wheaton
12.	FRL (Filter regulator Lubricator)	Janatics/ Festo/ Ingersoll
13.	Vent Filter for Dosing Bottles, 0.2 micron, PTFE	Sartorious/ Millipore/ pall
14.	Non Return Valve	Leader/ Alfa Laval
15.	Safety Relief Valve for Dosing metering Pump	Teleflo/Herose/ Ciprani Harrison
16.	Variable Frequency Drive	Siemens/Allen Bradley