User Requirement Specifications
Media Preparation Tank

Equipment ID: BF-MPT 01

Revision index

Revision	Date	Reason for Revision
00	09.12.2011	First Draft for Client's Review
01	2012-10-16	Format changed as per HLL requirement
02	2012-11-16	HLL comments incorporated: 1. Detachable Single spray ball assembly is added for both the vessel 2. Separate sampling assembly is added with dedicated sterilisation 3. double-roll lockable caster wheels for easy transportation
03	2013-01-03	Updated as per HLL comments, received on 2013-01-02 1. level switch/any interlock system for the safety operation of Magnetic Mixer.

		2. vertical view glass and level marking in the front view glass of the vessel
04	2013-01-10	1. BF-MPT 01 volume to be changed to 40L (GV) with at least 20L (WV) instead of 50L (GV) 2. Sampling valve assembly shall be removed from, only Sample port to be provided at the level of 8L (WV) to adjust pH manually 3. Steam trap to be removed as HLL and BCGVL has confirmed SIP is not required. 4. Safety valve to be removed from the tank 5. Temperature transmitter and Automatic Diaphragm valve is removed. 6. Peristaltic Pump to be removed. Transfer in 20L bottle will take place with Compressed Air. So one port is added
05	2013-04-10	Following major changes were incorporated as per the discussion with HLL meeting dated 09.04.2013 1. Independent fixed type Spray ball is provided for Media preparation tank instead of detachable type. 2. Independent fixed type Bottom magnetic GMP mixer provided for Media preparation tank instead of detachable type.
06	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.

nne pharmaplan	User Requirement Specifications			
	Equipment/System	Media Preparation Tank		
	Identification #	BF-MPT 01	**Document#**	URS/BF-MPT 01
	Effective Date	2013-04-10	**Revision#**	06

URS Annexure List

URS Annex No.	Detail
1.	Layout showing the location of installation of the Media Preparation Tank
2.	Tentative P&ID/ arrangement of the equipment
3.	List of Preferred MAKE of components

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1.0 Approval signatures

This document is prepared by the Process and Validation and GMP compliance team of "NNE Pharmaplan India for the project "Revival of BCG Vaccine Manufacturing Facility" (**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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Project Authority **BCG Vaccine Laboratory**		

2.0 Equipment description

The equipment described by this URS is a “MEDIA PREPARATION TANK” with a Gross volume of 40L.

The Tank shall be suitable to take water for injection (WFI) of 85°C for WIP and pre-weighed materials.

The Media preparation tank will be installed in a clean room of Class “C” and therefore have to meet all relevant requirements of clean room.

Design, function and control of the unit have to be GMP compliant.

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

S. No.	Description	Purpose
1.	Shell	To prepare and hold the Media Solutions
2.	Top closure	Torispherical
3.	Bottom closure	Torispherical
4.	Insulation	To avoid heat loss
5.	Cladding	Required to cover insulation
6.	Agitation	Bottom magnetic mixer arrangement with variable speed
7.	Provisions for different nozzle connections	To be used for WIP/Product/RM transfer

2.1 General Requirements

The general design must be hygienic, with no dead legs and no air pockets. The media preparation system must be fully drainable.

This Tank must be a floor-standing type with mounting legs on castor wheels. Following are the general requirements for a vessel.

a. **Dosing unit:** ALL powder raw materials are added into the vessel through the hand hole and WFI shall be added through the Spray ball

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 other process media.

c. **Vent Filter assembly:** The vessel shall be provided with the vent filter assemble comprising of hydrophobic type vent filter with SS housing . The housing shall be provided with the Staubli connectors for on line filter integrity testing of the filters. The same filter shall be used as a pre-filter for Compressed air. The pressure inside the vessel shall be monitored by a Pressure gauge on the top dish.

d. **Sampling Valve:** It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization

e. **Flush Bottom Valve:** It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It shall be provided with a separate line for pure steam sterilization

2.2 Purpose of use

Stainless steel tank used to prepare aqueous media solutions used in cell cultivation. It should also be possible to fill ready-made media into the media preparation tank and mix it with WFI.

The tanks have to be designed, constructed, built, installed and commissioned to prepare and store media solution in sufficient quantity.

Ingredients for media preparation are manually weighed and transferred into the media preparation tank and mixed with WFI. Then sampled and pH is adjusted manually.

General vessel specifications are as under:

Geometric volume	40 L
Working volume	25L
Material of Construction	SS316L
Dead volume	*Vendor to specify*
Max mixing volume	*25 L*
Min mixing volume	*5 L*
Media working temperature range	25°C – 85°C
Design temperature	150°C
Surface Finish	Internally Electro polished up to <0.4 Ra
	Externally Mechanically polished up to <1.2 Ra, matt finish

Nozzle schedule mentioned in sec 6.7

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 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 *Note: This section also includes the charging method of process media along with charging method for material input.*	
3.1.1 WFI (80% of the working volume) shall be added into the vessel. 3.1.2 The powder materials for the media preparation shall be charged in to the vessel through the hand hole (powder addition port) in the vessel 3.1.3 After mixing, WFI is added to make up the working volume.	
3.2 Brief Process Steps	
A) The tanks have to be designed to prepare and store media solution respectively in sufficient quantity and quality. a) After adding required amount of WFI, bottom mixer shall start manually b) The preparation tanks and transfer pipes will be washed &rinsed with hot WFI (85°C) or cleaned by CIP solution.	

Specifications	Remarks
3.3 Output & Discharging method	
a) The media will be transferred to the flasks manually and autoclaved.	
4.0 Productivity Requirement	
4.1 Desired/ suggested capacity	
At least 20 L working volume for Media Preparation Tank.	
4.2 Standard batch size	
Minimum mixing volume 5 L	
4.3 Change Over Time (if applicable)	
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 parameters.	
6.1.1 Adjustable agitation speed during the media preparation (VFD shall be provided) ***Note: Bottom Magnetic Mixer shall be of fixed type.***	
6.2 Failure mode detection	
Not Applicable	
6.3 In –Process control	
Sampling shall be done with sampling port, with the separate line for sterilization with Pure steam	
6.4 Level of instrumentation	
Not Applicable	
6.5 Batch data display and record printing	
Refer IRS (Installation Requirement Specification and Specific Instructions)	

Specifications	Remarks
6.6 GMP requirements (Others)	
6.6.1 The Vent filter housings in the vessel shall be provided sterilizing grade hydrophobic filter with housing with and Staubli connectors should be provided for on line integrity testing of the filters .	
6.6.2 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.	
6.6.3 Isolation valves should be provided wherever necessary	
6.6.4 All valves should be of sanitary manual Diaphragm valves	
6.7 Specific requirements	
6.7.1 In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.	
6.7.2 The vessel shall be provided with the following on the Top dish:	
• Vessel top to be Torispherical with nozzles required	
• Light port (preferably metal fused type)-1 no	
• Hand hole /sight glass - 1 no	
• Port for pressure gauge-1 no	
• Spray ball port - 1 no	
• Spare port - 2 no.	
• Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.2 micron hydrophobic of suitable size in SS316L construction.	
6.7.3 **On the lower wall side**:	
• Sampling port shall be provided at the level of 8L (W.V) – 1 no. (side wall)	
6.7.4 The vessel shall be provided with the following on the **Bottom dish**:	
• Vessel bottom to be Torispherically dished with a transfer line	
• Flush bottom valve with a separate line for sterilization using pure steam) -1 no	
6.7.5 Spray ball: • MOC shall be SS 316L. • Fixed type of Spray ball/s for covering entire area with 360^0 spray) ***(Vendor to specify the design).*** Systems with CIP shall be designed for 100% coverage of the internal surface areas.	

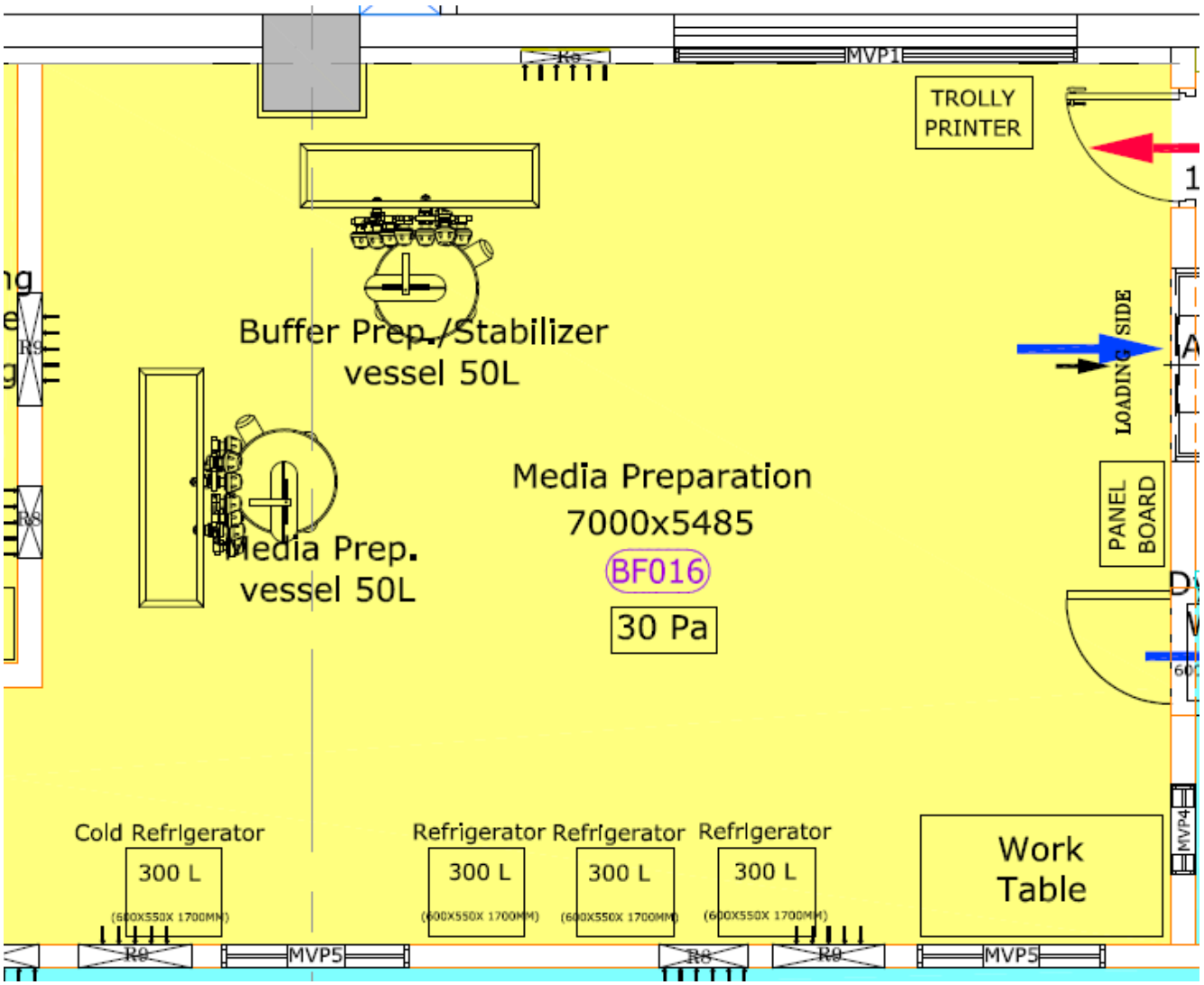
Specifications	Remarks
• Isolation Manual Diaphragm valve -1 no. shall be provided	
6.7.6 The Bottom magnetic GMP Mixer assembly shall consist of: • Variable speed 40-500 rpm A.C.motor with magnetic drive and VFD. Open end of the motor shaft have a flange fitted with a circular magnet. • Bottom mounted, magnetically coupled. • Magnetic mixer, suitable for liquids up to pH 1-14, Temp 130°C. • On/ off switch shall be provided for magnetic agitator with variable speed	
6.7.7 One dedicated sterile filter along with pressure regulator to be consider for compressed air to use it for transfer process media. Code 7 sterile filter and cartridge 0.22/ 0.2 µm hydrophobic of suitable size in SS316L construction with filter integrity ports	
6.7.8 Design Parameters: • Shell working Pressure- Full vacuum to 2.0 bar (g) • Shell working Temperature- 25-134°C • Shell design Pressure- full vacuum to 4 bar (g) • Shell design Temperature- 150 °C	
6.7.9 The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment.	
6.7.10 The CIP process shall be used for cleaning with mobile CIP trolley.	
6.7.11 Vessel shall be on 3 legs MOC: SS 304 with double-roll lockable caster wheels for easy transportation.	
6.7.12 Vendor shall provide flexible hoses to connect from vessel to floor drain.	
6.7.13 Vendor shall provide vertical view glass and level marking in the front view glass of the vessel. [For measuring the volume persists in the media vessel]	
7.0 Constraints	
7.1 Equipment location and available space	
This equipment will be installed in the Media preparation area of Revival of BCG Vaccine Laboratory at Guindy, Chennai. **Equipment Location:** **Floor:** BF016 **Room dimension :** 7000mm x 5485mm **False Ceiling height:** 3000mm The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.** **Physical condition of the rooms:** Media Preparation Room 1. Class: EU Class “C” 2. Differential Pressure: 30 Pa Absolute	

Specifications	Remarks
3. Temperature maintained: 22°C ±2°C 4. Relative Humidity: <55% RH	
7.2 Utility	
a) Electricity:1.10 kW (Report requirement) b) Water for Injection@3 bar_____ (Report Requirement) c) Pure steam@2.5 bar_____ (Report Requirement) d) Compressed Air@8-10 bar_____ (Report Requirement)	

8.0 Abbreviation

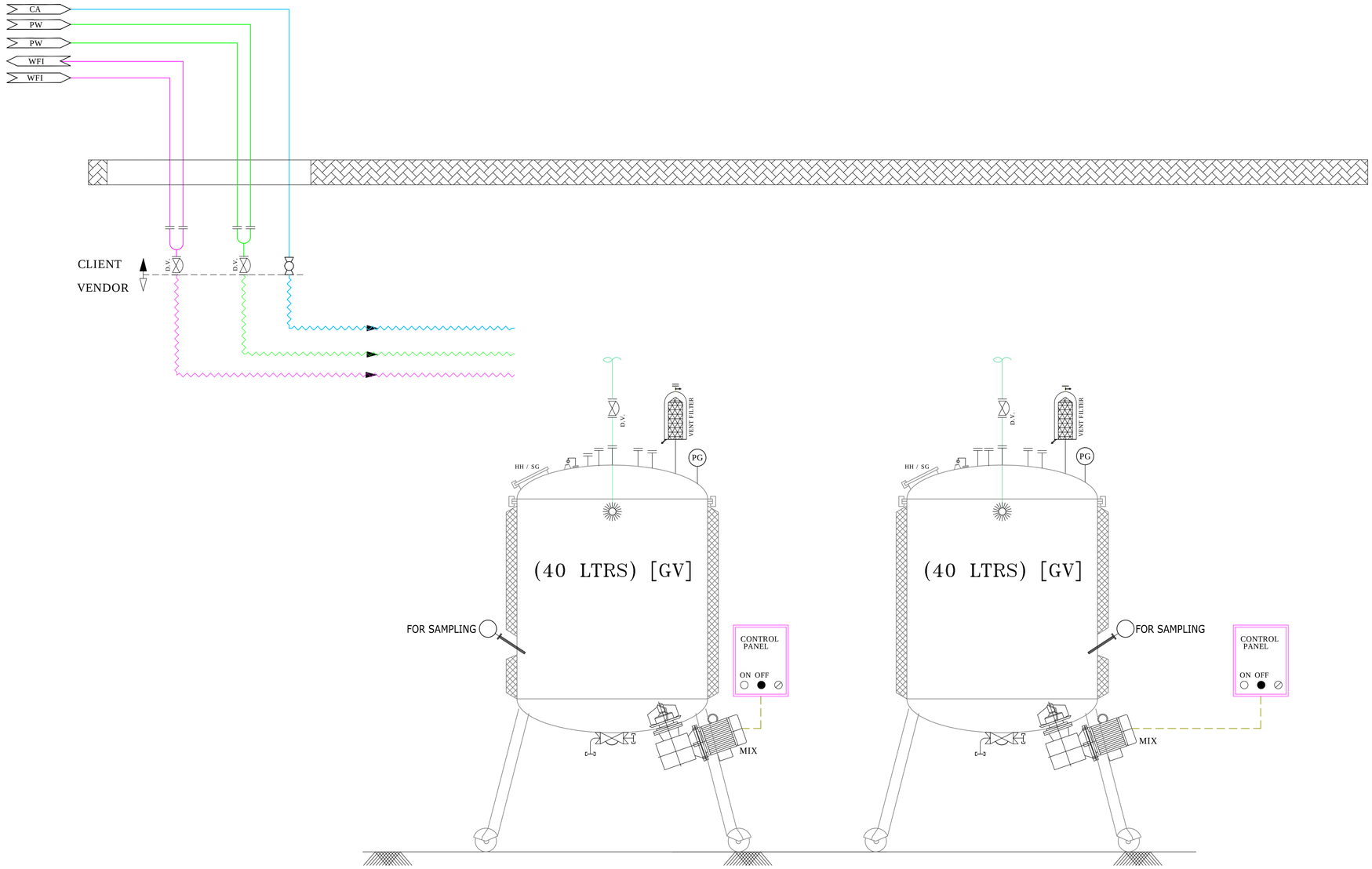
Terms	Abbrevation
^{0}C	Degree Centigrade
BCGVL	BCG Vaccines Laboratory
MPT	Media Preparation Tank
HLL	HLL Lifecare Limited
HMI	Human Machine Interface
ISO	International Standards Organization
MOC	Material Of Construction
NPI	NNE Pharmaplan India
PID	Proportional Integral Derivative
RPM	Revolutions Per Minute

URS ANNEXURE 1: LAYOUT SHOWING THE LAYOUT AREA
Room No.: BF016



URS Annexure 3: List of preferred make of components

S. No	Description	Make
1.	Manual Diaphragm Valve, SS 316L	Gemu/Saunders(Crane)/Burkert
2.	Flush bottom Valve	Gemu/Novaseptic
3.	Sampling Valve	Burkert/Alfa laval/novaseptic
4.	Magnetic Mixer	Alfalaval/Novaseptic
5.	Control Panel with Movable Trolley, SS 304 for Bottom Magnetic Mixer	Allen Bradley/Siemens/ ABB
6.	Silicon Braided Hose with TC End Connection	Integra/Alfa laval/AMI Polymer
7.	Vent Filter Cartridge	Millipore / Sartorious/ Pall
8.	Filter Integrity Connector	Millipore / Sartorious/ Pall
9.	Variable Frequency Drive	Alen Bradley /Siemens/ABB
10.	Spray Ball	HAKE/Lechler

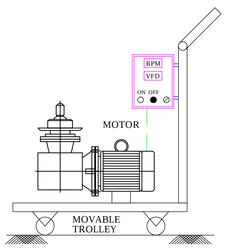


MEDIA PREPARATION TANK (BF-MPT 01)

BUFFER & STABILISER PREPARATION TANK (BF-BPT 01)

LEGEND

COLOUR & Symbol	DESCRIPTION
	WFI - WATER FOR INJECTION
	PW - PURIFIED WATER
	CA - COMPRESSED AIR
	PLC - LINE
	MANUAL BALL VALVE
	MANUAL DIAPHRAGM VALVE
	ACTUATED DIAPHRAGM VALVE
	SPRAY BALL
	FLUSH BOTTOM VALVE
	VENT FILTER
	TRI CLOVER CLAMP
MIX	MIXER
PG	PRESSURE GUAGE



NOTE:
1: FIXED CONNECTIONS
VESSEL WILL BE ATTACHED TO STEAM TRAP ASSEMBLY

Rev.	Date	Changed	Checked	Kind of revision	No. Of Prints	Date	Issued To
03	2013-04-10	SAPL	NVNG	Following changes incorporated as confirmed by HLL during meeting 09-04-2013 1. Fixed type of spray ball 2. Fixed type of bottom magnetic GMP mixer.	--	--	--
02	2013-01-10	NHSG	NVNG	Following changes as per MOM dated 2013-01-10: 1.BF-BPT 01and BF-MPT 01 volume to be changed to 40L (GV) with atleast 20L (WV) instead of 50L (GV) 2. Sampling valve assembly shall be removed from, only Sample port to be provided at the level of 8L (WV) to adjust pH manually 3. Steam trap to be removed as HLL and BCGVL has confirmed SIP is not required. 4. Safety valve to be removed from the tank 5. Temperature transmitter and Automatic Diaphragm valve is removed. 6. Peristaltic Pump to be removed. Transfer in 20L bottle will take place with Compressed Air. So one port is added	--	--	--
01	2012-11-07	NHSG	NVNG	1.Detachable Single spray ball assembly is added for both the vessel 2. Separate sampling assembly is added with dedicated sterilisation	--	--	--

File name :
Originated From Drg. No :

Project:
REVIVAL OF BCG VACCINES LABORATORY GUINDY, CHENNAI

Project No.: 110729
Location CHENNAI

nne pharmaplan®
NNE Pharmaplan India Limited
#14, Achiah Shetty Layout,
Bangalore - 560 080., INDIA.

Description:
P&ID FOR MEDIA PREPARATION TANK

	Date	Name
Drawn	1.05.2012	BHBH
Checked	1.05.2012	NHSG/ NVNG
Approved	1.05.2012	NVNG
Scale-NTS	Units : mm	Size : A4

Drawing no: NPI/110729/EQP(P&ID)/BF-BPT 01
Rev. 03

Note: This is an indicative drawing, final P&ID shall be given by the vendor.