User Requirement Specifications
Blending vessel

Process Code	Area	Equipment code	Qty(Nos)	Capacity
F	Formulation	F-BLV 01	1	750 L(G.V)

nne pharmaplan	User Requirement Specifications				
	Equipment/System	Blending vessel			
	Identification	F-BLV 01	**Document**	URS/F-BLV 01	
	Effective Date	2013-07-11	**Revision**	08	

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Blending vessel in the Formulation block
2	P&ID as separate URS annexure
3	List of preferred MAKE of components
4	Transfer philosophy from Blending vessel to buffer vessel in Filling room

Table of Contents

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 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.Divya.H Project Engineer-Biotech NNE Pharmaplan India Ltd.		

Checked by		
Name/ Designation	**Signature**	**Date**
Dr. Naveen Nagaraj Sr. Project Manager - Head Biotech Division NNE Pharmaplan India Ltd.		
Mr. Vikas Katiyal GM-Head COC Vaccines NNE Pharmaplan India Ltd.		

Approved by		
Name/ Designation	**Signature**	**Date**
Mr.Narendra Prasad Director-Technical NNE Pharmaplan India Ltd		
HLL Lifecare Limited		

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

2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a "BLENDING VESSEL" with a Geometric volume of 750 L. The Tank shall be suitable to take water for injection (WFI) of 30°to 85°C and pre-weighed materials.

The Blending vessel in the Formulation block is used to blend the antigens of Diphtheria, Pertussis and Tetanus along with gel(sterile) and saline.

The vessel shall be designed, constructed, built, installed and commissioned to hold solutions filtered, in sufficient quantity and quality. This shall include appropriate control & monitoring systems.

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

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

2.0.1 **TABLE 1**

S. No.	Description	Purpose	MOC
1	Shell	Cylindrical to hold and blend the antigens	SS316L
2	Top closure	Torispherical dish	SS316L
3	Bottom closure	Torispherical dish	SS316L
4	Jacket	Hollow type, only for cylindrical shell	SS304
5	Insulation	To avoid heat loss, only for cylindrical shell	Mineral wool
6	Cladding	Outer cover to Insulation	SS304
7	Agitation	Vibromixer (top mounted)	SS316L
8	H/D ratio	1.2:1.0	-

2.0.2 **TABLE 2**

Sl.NO	Description	Specification
1.	Geometric volume	750L
2.	Maximum working volume	500L
3.	Quantity	1 No
4.	Min mixing volume	180 L(Vendor to confirm)
5.	Working temperature range	20-134^{o}C
6.	Rise in temperature (heating capacity)	*4^{0} C per minute*
7.	Fall in temperature (cooling capacity)	*4^{0} C per minute*
8.	Temperature control deviation	±0.1^{o}C
9.	Surface Finish	Internally Electro polished up to Ra ≤0.6 µm
		Internal finish of the interconnecting piping: Ra < 0.6 µm
		Externally Mechanically polished up to Ra ≤1.2 micron m(matt finish)

2.0.3 The Blending vessel is supplied along with all the necessary piping, valves and instrumentation. The equipment to be floor-mounted on 3 legs. The control panel is floor-mounted on legs.

a) Dosing Unit for Antigen 1: Antigen 1 will be added to the Blending vessel through sterile valve assembly using Peristaltic pump.

b) Dosing Unit for Antigen 2: Antigen 2 will be added to the Blending vessel through sterile valve assembly using Peristaltic pump

c) Dosing Unit for Gel: Sterile Gel will be added to the Blending vessel through sterile valve assembly using Peristaltic pump

d) Dosing Unit for saline: The Saline will be added to the Blending vessel through sterile valve assembly by pressure transfer. 0.45 µ on line sterile filter unit should be provided in the inlet line for the clarification of the saline.

e) Dosing Unit for Acid: Acid will be added to the Blending vessel through sterile valve assembly using Peristaltic pump. The pH shall be controlled by using :

- In-situ sterilizable pH gel electrode, connecting cable and pH controller (Same for acid and alkali)
- By the addition of acid

f) Dosing Unit for Alkali: Alkali will be added to the Blending vessel through sterile valve assembly using Peristaltic pump. The pH shall be controlled by using

- By the addition of Alkali

g) Air supply: Compressed air inlet should be provided with the following:

- Independent Sterile filter with SS316L housing and control valve
- Pressure reducing valve

h) Temperature Control: The temperature during ***blending*** shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket with electric heater and steam and a circulation pump. Temperature control during blending should be 30 ºC (tolerance limit: ±0.1 ºC) & during sterilization (tolerance limit: ±0.1 ºC)

- The system consists of closed loop pressurized thermostat system with recirculation pump, 2 heat exchangers for heating and cooling alternatively which provides a high flow through the hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable).
- Electrical heater ,Heat exchanger and steam for cooling water & chilled water for operation temperature
- Safety relief valve
- Bourdon type pressure gauge for jacket utility
- Pneumatically operated valves for steam and cooling water/ chilled water

i) Pressure Control: Pressure of the vessel and CIP/SIP steps shall be controlled by the following:

- Compound Pressure gauge for vessel and Pressure transmitter
- Back pressure control valve in the exhaust line

j) Mixer: The vessel shall be designed with top mounted mixer as per process requirement. The mixer shall be Vibromixer type. It works on reciprocating motion The mixer shall be gear free to

ensure smooth operation. Mechanism should provide minimum shear even at high speeds. The supporting structure shall be included to hang or support the motor from the top.

The Vibromixer specifications are as follows:

a. Vibromixer type: E3, vertical vibration@50-60 times/second with Amplitude controller

b. Vibro drive

c. Movement-one cone upwards and one cone downwards

d. Speed: 55% vibration(However, vendor to confirm)

e. Power requirements: 220 V,3.3A;50 Hz

k) Vent Line/Exhaust Line: Blending vessel vent line includes

- A sterile vent filter with SS housing & a control valve.
- A Rupture disc is mounted on top of the Blending vessel to relieve excess pressure during operations.
- Compressed air inlet for vent filter
- Back pressure control valve in vent/exhaust line (Also mentioned under pressure control)

l) Flush Bottom Valve: It is also Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It should be sterilizable type valve.

m) Sampling valve: It should be zero dead leg type valve attached directly to the lower wall of the vessel, with a provision for SIP. The diaphragm shall be of PTFE type

n) CIP (Cleaning – In – Place): The vessel shall be cleaned by using a Mobile CIP trolley.

- SS 316L Spray ball 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.
- The CIP control system can be integrated with the control system of

  Vessel.

o) SIP (Sterilization – In – Place) : The blending vessel shall be designed for in built SIP.

The following principles will be applied for SIP of the system:

- The vessel should be provided with ESIP/FSIP features
- The exhaust air filters to be sterilized along with the vessel.
- The sampling valve and Flush bottom valve can be sterilized independently.
- All addition valve groups for antigen 1, antigen 2, acid, alkali, gel and saline are sterilized along with the vessel and should be independently sterilizable.
- The sensors should be reusable and sterilizable type.
- Cleaning and sterilization of fixed piping from Blending to Filling room is required and once through CIP for fixed pipe line.
- SIP piping from header to the vessel skid: SS 316L. Ra < 0.6 µ
- Pressure reducing valve for pure steam lines
- SIP should be automatically controlled through PLC and HMI combination.

p) Controller: - PLC Based Controller(Non-editable data format to be obtainable)with a 15" HMI (Displaying data trends as Graphs, synoptic view of running parameters etc)

q) The HMI shall be touch screen type (Provision for manual operation also to be provided). All setting shall be user adjustable.

- HMI screen size shall be of 15 inches
- Human machine interface must be used to enter the process details, which should appear in the print out.
- All critical alarms
- All Critical parameters & interlocks
- Addition of the antigen1 , antigen 2 ,acid,alkali,gel and saline
- All Recipes/ sequences (Process, CIP , SIP, transfer etc)
- P&ID of the vessel along with instrumentation details
- Login details
- HMI screen showing simulation of valves

r) SCADA Software: - Windows based Supervisory Control and DATA Acquisition (SCADA) Software for monitoring and control of various process parameters. The Software capable for remote logging and process control. The system should be suitable for supervisory control of at least 1 blending vessel. The system, designed for process validation, batch management features, multi-parameter display, time based programming of set points, regulation of process by both measured and calculated variables (by using equations), equation writing and its integration for control of process parameters, ability to set both high and low limits and alarms, graphic / plotting, off-line data integration (Non-editable data sheet and batch reports). Options for manual override of all values, set-points and Process parameters during the process.

2.0.4 **Nozzle schedule :**

1. Top Dish

The Blending vessel top dish shall have:

a) Pressure gauge - 1 No
b) Port for pressure sensor along with Pressure transmitter- 1 No
c) Port for Spray ball - 2 Nos
d) Port with Vibromixer (With flange welded to dish)-1 No
e) Spare port(TC clamps with gasket)-2 Nos
f) Hand hole - 1 No
g) Rupture disc- 1 No
h) Light glass with halogen lamp Bolted with gasket – 1No
i) Compressed air inlet-1 No
j) Port for Exhaust with vent filter (TC clamps with gasket)-1 No

2. Upper wall side:

The Blending vessel's upper wall side normally will have :

a) Differential pressure(DP) sensor port-1 No
b) Jacket outlet (Non – sterile DN Union connection) -1 No
c) 4 way sterile addition port for antigen 1-1 No
d) 4 way sterile addition port for antigen 2-1 No
e) 4 way sterile addition port for Gel -1 No
f) 4 way sterile addition port for saline -1 No
g) 4 way sterile addition Acid addition port-1 No
h) 4 way sterile addition Alkali addition port-1 No
i) Vertical view glass-Bolted with gasket-1 no
j) Safety relief valve on Jacket outlet line-1 No
k) Bourdon Pressure Gauge(On Jacket outlet line)-1 No

3. Lower wall side:

The Blending vessel lower wall side shall have the following ports

a) Jacket inlet(Non – sterile DN Union connection)-1 No
b) 25 mm Temperature sensor port (15 degree knuckle port)-1 No
c) 25 mm pH sensor port(15 degree knuckle port)-1 No
d) Port for Sampling valve, sterilizable- 1 No
e) Spare Port – 25 mm 15 degree knuckle port -1No

4. Bottom Connections

a) Port for Flush bottom valve,sterilizable-1 No
b) Differential pressure(DP) sensor port- 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, 4.1.13,4.1.17
- **Sec 5.1 Table 2**
  - **Sl.NO 2 and 3 :**FDA guidance for industry
  - Sl.NO 5 CE Conformity,
  - Sl.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
  - Sl.NO 8 ISO 14664
  - Sl.NO 9 ISO 8362
- Sec 5.4.1 All metallic product contact / critical surfaces should be constructed of SS316 L grade with internal mirror finish (< 0.5m Ra for filling line and < 0.8m Ra for lyophiliser) and external surface matte finish (< 1.2µ Ra)

  For surface finish values refer the point 9 under Sec 2.0.2 Table 2 mentioned in the URS
- Sec 5.6

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. 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.
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 become 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 Specification and Specific Instructions with URS; NPI_110831_IRS_PII_01
12.	Refer Tender document with URS; NPI/110831/EQP/TD/02

	Specifications	Remarks
3.0	**PROCESS DESCRIPTION**	
3.1	**Input & Charging method**	
3.1.1	The liquid material (ingredients) used for the preparation of the blending solution shall be fed into the vessel aseptically through the sterilizable valve assembly.	
3.2	**Brief Process Steps**	
	The tanks have to be designed to prepare and store blending solution respectively in sufficient quantity.	
3.2.1	Antigen 1 and Antigen 2 along with Aluminium phosphate gel are added into the vessel through the different sterilizable valve assemblies by using Peristaltic pumps	
3.2.2	Saline shall be added into the blending vessel through the sterile valve assembly by pressure transfer from the Buffer preparation vessel.	
3.2.3	The antigens 1 and 2, gel and saline(sterilized in 0.45µ SFU in the inlet) are blended well.	
3.2.4	After mixing the antigens, the solution is maintained at 30°C.	
3.2.5	During stirring the pH value and temperature inside the tank is measured	
3.2.6	Samples can be drawn through sampling(Diaphragm) valves.	
3.2.7	Recirculation of blended solution shall be provided within the blending vessel using Peristaltic pump.	
3.3	**Output & Discharging method**	
3.3.1	The blended antigen solution from the Blending vessel will be flushed out through the Flush bottom valve and then transferred using the Peristaltic pump through the fixed piping to the buffer vessel in the filling room. **Note:** With reference to URS Annexure II-Drawing No-NPI/110831/EQP(PID)/F1-BLV 01, the valve V1(Pneumatic diaphragm valve) should be in the Blending vessel vendor's scope. Further vendor to provide distance piece with TC for valve V1.	
3.3.2	The hold up volume in the fixed pipe line shall be purged using sterile Compressed air.	
4.0	**PRODUCTIVITY REQUIREMENT**	
4.1	**Desired/ suggested capacity**	
	750 L Geometric volume	
4.2	**Standard batch size**	
	Maximum Working volume: 500 L Min Working volume:180 L(Vendor to confirm)	
4.3	**Change Over Time**	
	Not Applicable	

Specifications		Remarks
4.4	**Others(if any)**	
	Not Applicable	
5.0	**Containment**	
	Not Applicable	
6.0	**GMP REQUIREMENTS**	
6.1	**Process control**	
6.1.1	Temperature of product during the blending	
6.1.2	Temperature of the jacket utility(both indication and control)	
6.1.3	Pressure of the vessel during blending	
6.1.4	Pressure indication(only) for the jacket using Bourdon type pressure gauge	
6.1.5	pH of the blending solution	
6.1.6	Speed of the Mixer during the blending	
6.1.7	Level of the fluid in the vessel	
6.1.8	Flow switch for jacket utility	
6.1.9	CIP/SIP process parameters	
6.1.10	Duration of cycle(CIP,SIP)	
6.1.11	Pneumatically actuated valves in the individual Feed lines, WFI, PW, CIP, Buffer, Pure steam and discharge line.	
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: (if it exceeds by 0-10% (i.e. tolerance limit) of the set point value):		
6.2.1.1	Mixing speed is out of set range	
6.2.1.2	pH is out of set range	
6.2.1.3	Temperature is out of set range	
6.2.1.4	Low/high pressure	
6.2.1.5	Low/high level/volume	
6.2.1.6	Abrupt change in temperature in a particular time	

Specifications		Remarks
6.3	**In – Process control**	
6.3.1	Should have provision for sampling of product solution.	
6.3.2	Should have provision of indication of Blending cycle time, temperature, pH, pressure, etc through HMI.	
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 of the product	To monitor, indicate and control the product temperature	Temperature probe with indicator and controller
Temperature of the jacket	To monitor, indicate and control the jacket temperature	Temperature probe with indicator and controller
pH	To monitor the pH of the blending solution	pH probe/transmitter
Level	To monitor the level of the product in the vessel	DP sensor
Amplitude/ Mixing Speed	To control Vibro mixer speed	Variable frequency drive with indicator
Pressure	To monitor, indicate and control the pressure of vessel and for CIP/SIP	Pressure transmitter with indicator and controller
Time	Timer control of process and monitoring CIP/SIP process	Timer (HMI)
Dosing	To feed antigens1 and 2, acid,alkali,gel for recirculation of blending solution	Peristaltic pump(5 Nos)

6.5	**Batch data display and record printing**	
	Refer Installation requirement specifications	
6.6	**GMP requirements (Others)**	
6.6.1	The air housings in the vessel shall be provided with Staubli connectors for in-situ integrity testing of the vent 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.	
6.6.3	All nozzles shall be flushed to the wall on closure.	

Specifications	Remarks
6.6.4 Nozzle length shall be minimized (less than 2D) to avoid cold spot during steam sterilization.	
6.6.5 Bottom discharge and sampling valve shall be zero dead leg type.	
6.6.6 Utility operation shall be preferably automatic and valves shall be placed inside of aseptic area.	
6.6.7 Steam traps shall be provided where ever required at the system.	
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 Blending vessel outlet should be provided with recirculation loop with the pump.	
6.7.3 Silicone tube, hose nipples should be provided wherever is necessary.	
6.7.4 Provision should be provided to purge the hold up volume using compressed air, in the fixed pipe line from Blending vessel to filling machine.	
6.7.5 Design Considerations: 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- 130°C 6.7.5.8. Jacket design Pressure- Vendor to specify 6.7.5.9. Jacket design Temperature- Vendor to specify	
6.7.6 Nozzle shell shall be seamless.	
6.7.7 Nozzles, adaptors, instrument shall comply to ASME BPE compliant.	
6.7.8 Total motor drive assembly with SS304 cover with TEFC eff 1.	
6.7.9 Mechanical lifting device shall be provided to lift the top dish and to support the top mounted Vibro mixer. The supporting structure shall be included to hang or support the motor from the top.	
6.7.10 For hot and cold pipe lines ¾ “thickness armaflex material insulation shall be provided.	
6.7.11 The 2 Nos of fixed speed Peristaltic pumps are required for the addition of antigen 1 antigen 2, Gel @rate of 200 L/hr, with the pump head compatible with the tube sizing:12/17 mm.	
6.7.12 2 Nos of fixed speed peristaltic pumps are required for the addition of acid and alkali with	

Specifications	Remarks
the pump head compatible with the tube size:3.8/7 mm	
6.7.13 1 No of fixed speed Peristaltic pump is required for the recirculation of blending solution into the blending vessel @ rate of 280 L/hr with the pump head compatible with the tube size :9.6/14.4 mm **Note:** Vendor to suggest viable and economical option for peristaltic pump having SIPable option.	
6.7.14 Performance criteria during FAT/SAT: a. Media hold with process simulation including all peripheral equipments SAT b. Pressure hold test should be performed during FAT c. Spray ball coverage test during FAT d. Thermal mapping e. All control system simulation and tuning of all control loops f. All FAT/SAT IQ,OQ as per IRS	
7.0 CONSTRAINTS	
7.1 Equipment location and available space	
This equipment will be installed in the Formulation block of Revival of DPT vaccine manufacturing facility at PII, Coonoor as follows: **Block** Formulation Block **Floor** Ground floor **Room area:** 43 m^2 **Room No.** F1G057 **False ceiling height:** 3000 mm **Physical condition of the room:** 1. Class: EU Class "B" 2. Differential Pressure:55 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: NMT 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 Plant steam - 130 °C - 150°C at 3 – 3.5 bar (g) ----------(Report requirement)	
7.2.2 Pure steam - 121 °C - 130 °C at 2.4 bar (g) ----------(Report requirement)	
7.2.3 WFI (Hot loop) - 80-85°C at 2 bar (g) ----------(Report requirement)	
7.2.4 Purified Water - 28 - 30°C at 2.5 bar (g) ----------(Report requirement)	
7.2.5 Cooling water - 28°C -30°C at 3 bar (g) ----------(Report requirement)	

Specifications	Remarks
7.2.6 Chilled water -8°C to 12°C at 3 bar (g) ----------(Report requirement)	
7.2.7 Electricity - Vendor to specify----------(Report requirement)	
7.2.8 Compressed air- 6.0– 8.0 bar (g) ----------(Report requirement)	
Note: Utility consumption to be specified by the vendor, in case if there is a deviation in the values mentioned above.	

8.0 ABBREVIATION

Abbreviation	Definition
PII	Pasteur Institute Of India
BLV	Blending Vessel
CIP	Clean In Place
SIP	Sterilization In Place
GMP	Good Manufacturing Practices
HLL	HLL Life care Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization
HMI	Human Machine Interface
PLC	Programmable Logic Controller
NMT	Not More Than

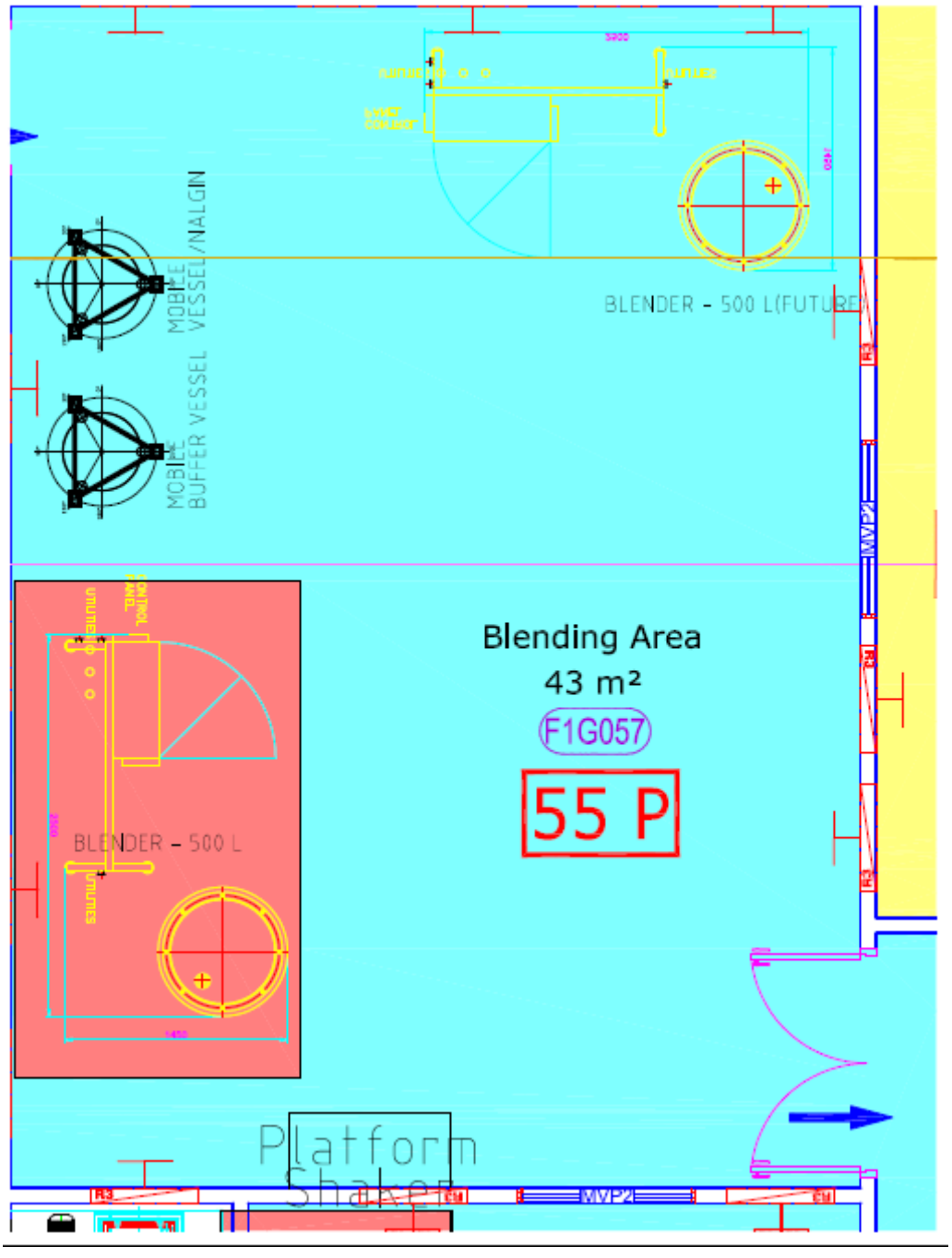
Revision index

Revision	Date	Reason for Revision
00	2012-06-01	First Draft for Client's Review
01	2012-11-23	Format changed as per HLL requirement
02	2013-02-04	Updated as per PIIC/HLL comments as per MOM 2013.01.22 and 2013.03.23
03	2013-03-21	Updated as per revised MOM dated 2013.01.22 and 2013.01.23, received on 2013.03.18
04	2013-04-23	Updated as per the comments received from HLL on 2013.04.22
05	2013-05-16	As per the Telephonic discussion with HLL on 2013.05.13.Following major changes are incorporated: • Point 2.0.3: Temperature control modified ➢ Both heat exchanger and steam required for temperature control ➢ Bourdon type pressure gauge for jacket utility is added • Point 2.0.3: CIP modified as ➢ CIP recirculation loop and pump removed ➢ CIP Piping from header to vessel removed • Point 2.0.3 SIP modified by deleting the repeated points. • Point 2.0.3 Controller modified with the requirement of Non-editable data format and single PLC. • Point 2.0.3 HMI size changed to 15" and changed as HMI screen size showing simulation of valves • Sec 6.1 Pressure indication(only) for jacket using Bourdon type pressure gauge • Sec 6.4 ➢ Pressure transducer changed to transmitter ➢ No. of dosing pumps changed • Point 6.7.9 retained • Point 6.7.10,6.7.11,6.7.12 Specifications of dosing pumps modified • Point 6.7.14 Performance criteria during FAT/SAT modified • URS annex 3: List of preferred MAKE of components modified ➢ Pressure sensor deleted ➢ Conductivity sensor deleted ➢ pressure regulator-FESTO retained ➢ Pre-filter cartridge and vent filter cartridge: PALL included in the MAKE list , Airtech and Fine airsys removed ➢ Filter housing: PALL included in the MAKE list

Revision	Date	Reason for Revision
		➢ Diaphragm valve(manual): Avcon and Saunders deleted from the MAKE list ➢ Sampling valve and Flush bottom valve: GEMU included ➢ Control panel deleted from the list ➢ Electrical motor deleted
06	2013-06-21	As per the comments from HLL by email on 2013-06-12 & 2013-06-21 • Comments updated • 0.45 micron sterile filter unit is provided for on line clarification of saline before adding into the blending vessel
07	2013-06-27	As per comments received from HLL on 2013-06-27 ➢ Sec 2.0.3 d) and 3.2.2 Peristaltic pump to transfer saline into the blending vessel is deleted and the same shall be done by pressure transfer is included. ➢ Sec 2.0.3 o) SIP • Included that the addition valve groups shall be Independently sterilizable ➢ Sec 2.0.3 r) Non-editable data format included ➢ 6.7.9 Mechanical lifting of top lid included
08	2013-07-11	As per the mail confirmation received from HLL on 2013-07-11: ➢ Schematics of Transfer philosophy from Blending vessel to buffer vessel in Filling room is included as URS Annexure 4

URS Annexure 1: LAYOUT OF FORMULATION BLOCK

Room No: F1G057



URS Annexure 3: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
A	**INSTRUMENTATION**	
1	PLC	Allen Bradley/ Siemens
2	Operator Interface/HMI	Allen Bradley/ Siemens
3	Temperature transmitter	Radix/ Yokogawa/Emerson
4	Temperature sensor	NEGELE
5	p H sensor	METTLER TOLEDO/E&H/Hamilton
6	Pressure transmitter	Wika /Dwyer/Sensocon
7	Pressure regulator	FESTO
8	Temperature indicator	Radix/ Wika/ Waaree instruments
9	Steam trap	STERIFLOW/ITT
10	Printer	Epson/ HP/ Canon
11	DC source	Shavision/ Yokogawa/ Emerson
B	**MECHANICAL**	
12	Pressure gauges	WIKA/Denver/Negele
13	Pre air filter cartridge	Sartorius/PALL / Millipore
14	Vent filter cartridge	Sartorius/PALL / Millipore
15	Filter housing	Sartorius/ PALL/Millipore
16	Spray ball	HAKE
17	Diaphragm valve(Manual)	GEMU/Burkert
18	Ball valve(Manual)	Modentic/Saunders/Alfa laval
19	Non return valve	Modentic/Saunders/Alfa laval
20	Sampling valve	Novaseptic/GEMU
21	Flush bottom valve	Novaseptic/GEMU
22	Safety relief valve	HEROSE/SS Spirax /Amtech valves
23	Rupture disc	Zook/Elfab/ Fike
24	Flow switch	Orion/ Wika/Emerson
25	Rotameter	GEMU/Allborg
26	Peristaltic pump	Watson Marlow/Masterflex
27	Vibro mixer	BBI / Graber & Pfenninger / Rutten engineering

SL.NO	DESCRIPTION	MAKE
C	**PNEUMATIC**	
28	Diaphragm valve(Automatic)	GEMU / ITT
29	Angle seat valve(Automatic)	GEMU / ITT
D	**ELECTRICAL**	
30	Lamp	PAPENMEIER