User Requirement Specifications
Sterilization - Autoclave

Block Code	Area	Identification #	Qty (Nos)	Internal Chamber Dimensions (W x H x D) in mm	Door type
B1	Multiple Bacterial Bulk block – Hep B	B1-SAT-01, B1-SAT-02	02	1200 x 1200 x 1800	Double door with horizontal sliding
B1	Multiple Bacterial Bulk block – Hib	B1-SAT-03	01		
F4	BCG Bulk and Formulation block	F4-SAT-01, F4-SAT-02,	02	900x 900 x 900	Double door with horizontal sliding

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URS Annexure List

URS Annex No.	Detail
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2.	List of Preferred Make of Components
3.	List of critical items to be supplied along with the package

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 and QA and authorized by the appropriate Project Authority.

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2.0 EQUIPMENT DESCRIPTION

Autoclave for sterilization should have following main features:

- Operation programs for liquid, solid and porous materials

Package Unit (PU) including the following:

- Sterilizer chamber
- Supporting structure
- Integrated vacuum system
- Filters for process air and for exhaust air
- Piping (valves, safety devices, filters, steam traps, pipes, fittings, etc.)
- Sanitary type pressure reducing valve in pure steam inlet (for regulating the pure steam inlet pressure to the autoclave chamber as the header pressure is more than 3.0 kg/cm^2).
- All mating flanges/fittings, gaskets, bolts and screws for utility supplies, returns and drain
- Instrumentation
- The unit should be direct steam heated as well as jacket steam heated and designed for full vacuum.
- Control system with printer for batch report and color trend printing
- Bio shield to seal the sterile and non-sterile areas
- One flexible probe to be provided to perform product cycle development and auto sequence to be provided.
- Small valve for steam pulsing should be provided in the steam sterilizer design

Design, function and control of the units has to be **GMP compliant**

All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.11, 4.1.13, 4.1.17
- **Sec 5.1 Table 2**
  - SI.NO 5 CE Conformity,
  - SI.NO 7 ANSI/NSF 49-2008,
  - SI.NO 8 ISO 14664
  - SI.NO 9 ISO 8362

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 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-15

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 The sterilizer should be suitable for sterilization of various items such as: • Glass containers • Liquid media in glass • Silicon tubing's, Gaskets and siphon sets • Clean room garments • Machine components • Stoppers and seals	
3.1.2 **Chamber Carriages:** The unit should be provided with 1 no loading carriage which should be made of SS 316L and it should be with removable / adjustable perforated shelves (4 nos.) of SS 316L, which can be positioned according to the height of the goods. The carriage should be provided with 4 wheels, which would withstand the high temperature inside the autoclave. It should be designed to slide easily from chamber to trolley.	
3.1.3 **Loading & Unloading Trolley:** The trolleys (2 nos.) should be made of SS 304 SS round pipes and its base should be with 2 nos. of heavy duty swiveling at backside of the trolley and other 2 nos. are fixed type castor wheels made of polyurethane and fitted in a stainless steel bracket. The height adjusting arrangement should be provided for adjusting level with the sterilizer. The trolley should have locking arrangement with carriage as well as with chamber. The unit along with all fitting should be mounted on SS 304 sturdy tubular structure having SS 304 level adjusting flanges.	
3.1.4 Articles for sterilization will be loaded manually in the autoclave so that all articles can come in contact of the sterilizing steam using movable carriage	
3.1.5 There should be a pair of SS 316L railing inside the chamber. Rail design should be suited for smooth and easy loading and unloading of carriage. The rail should be of removable type for easy cleaning.	
3.1.6 The plane of chamber and the plane of the trolley should be same, so that the loading/unloading carriage can be moved directly & smoothly in to the chamber. ***Loading level should be defined by the vendor.***	
3.1.7 Equipment parts, garments etc. will be packed in sterilizable bags before loading in the equipment for sterilization.	
3.1.8 Loading environment: • All sterilization autoclave loading will be from Grade C.	
3.2 Brief Process Steps	
Sterilization should have following steps 1. Loading 2. Initial Vacuum Pulsation	

Specifications	Remarks
3. Heating (Steaming) 4. Hold period (Sterilization) 5. Post vacuum 6. Drying 7. Unloading	
3.3 Output & Discharging method	
3.3.1 All sterilized articles will be unloaded from the unloading side by using unloading Trolley. 3.3.2 Chamber Carriage will be taken out and articles will be unloaded from the carriage. 3.3.3 All condensates and liquids should lead to common drain.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	

Sterilization Autoclave (SAT):

Sl. No	Area	Identification #	Internal Chamber Dimensions (W x H x D) in mm	Qty (Nos)
1	Multiple Bacterial Bulk block – Hep B	B1-SAT-01, B1-SAT-02	1200 x 1200 x 1800	02
2	Multiple Bacterial Bulk block – Hib	B1-SAT-03	1200 x 1200 x 1800	01
3	BCG Bulk and Formulation block	F4-SAT-01, F4-SAT-02,	900 x 900 x 900	02

Chamber total volume: Vendor to specify

4.2 Standard batch size	
Not applicable	
4.3 Change Over Time	
Not applicable	
4.4 Other Productivity Requirement	
Total sterilization cycle must not to exceed 2 hours.	
5.0 CONTAINMENT	
Not applicable	
6.0 GMP REQUIREMENTS	
6.1 Process control	
6.1.1 The equipment must operate and control the following process cycle:	

	Specifications	Remarks
	• Vacuum leak test cycle (As per HTM 2010)	
	• Bowie Dick cycle (17 min at 121 °C and 3.5 min at 135 °C)	
	• Standard sterilization cycle (loading → steaming → hold period→ slow/fast exhaust (for liquid cycle, the exhaust will be slow)	
	• Standard cycle 1- Liquid (123 °C)	
	• Standard cycle 2 -Fabric (134 °C)	
	• High-pressure high vacuum sterilization cycle (loading → steam/vacuum pulsing → heat up → hold period → exhaust → vacuum drying → vacuum break by sterile air.	
6.1.2	For the above processes following are the critical process parameters which must be controlled by the equipment	
	• Pre vacuum	
	• Pre pressure	
	• No. of Pre pulses	
	• Heat up	
	• Heat up hold	
	• Heat up control band	
	• Sterilization hold temperature	
	• Sterilization hold time	
	• Temperature control band	
	• Overshoot temperature	
	• Sterilization stop temperature	
	• Sterilization reset temperature	
	• Post vacuum start pressure	
	• Post vacuum	
	• Post vacuum hold time	
	• Vacuum break	

Specifications	Remarks
• No of post vacuum	
• Exhaust ON	
• Exhaust OFF	
• Process end pressure	
• Chamber pressure high and low	
• Jacket pressure high and low	
• Too long time for pre vacuum	
• Too long time for heat up	
6.2 Failure mode detection	
6.2.1 The Autoclave should be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1.1 If chamber vacuum leak test is failed	
6.2.1.2 If the chamber temperature overshoots	
6.2.1.3 If chamber temperature falls below specified level & the timer stops counting	
6.2.1.4 If chamber temperature falls further below specified level & the timer resets previously counted time	
6.2.1.5 If chamber pressure is greater than the set value	
6.2.1.6 Too long time for heat up	
6.2.1.7 Too long time for pre vacuum	
6.2.1.8 Too long time for post vacuum	
6.2.1.9 If vacuum pump trips	
6.2.1.10 Door pre-condition fails	
6.2.1.11 Failure in utility supply	
a) Compressed air pressure low	
b) Plant steam pressure low	
c) Pure steam pressure low	
d) Softened water pressure low	
6.2.1.12 Failure in data communication	

Specifications	Remarks
6.2.1.13 Vendor should propose detailed list of alarms and interlocks in Functional specifications. The alarms and interlocks list should be finalized with the final user during discussion of detailed engineering design of the equipment	
6.2.1.14 Emergency stop activated	
6.2.1.15 Power / UPS failure	
6.2.1.16 End of cycle and door opening after end of cycle need notification to operator for procedural control	

6.3 In –Process control

Manual diaphragm valves should be provided for sampling the pure steam & chamber condensate.
All necessary ports for steam quality testing as per EN 285 should be incorporated.

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/ Observation	Operation range	Desired Least Count	Extent of Instrumentation			
				Indication	Alarm	Control	Recording
Temperature (multipoint), min 6 Nos.	Chamber temperature	0°C to + 150°C	0.1°C	Y	Y	N	Y
Temperature	Chamber condensate drain	0°C to + 150°C	0.1°C	Y	Y	Y	Y
Temperature	Jacket temperature	0°C to + 150°C	0.1°C	Y	Y	Y	Y
Temperature	Air leak	0°C to + 150°C	0.1°C	Y	Y	Y	Y
Time	Sterilization time	On real time basis	1 Sec	Y	Y	Y	Y
Pressure	Chamber pressure and vacuum	Full vacuum to 2000 mbar	1.0 mbar	Y	Y	Y	Y
Pressure	Jacket pressure	0 to 5.0 bar	0.1 bar	Y	Y	Y	N
Pressure	Pressure across the sterilizing grade	0 to 2000 mbar	1.0 mbar	Y	N	N	N

Specifications								Remarks
	vacuum break filter							
Pressure	Main compressed air line for pneumatic control	0 to 10.0 bar	0.1bar	Y	Y	N	N	
Pressure regulating valve along with pressure gauge	Main Pure steam line for regulating the pressure	0 to 10.0 bar	0.1bar	Y	N	N	N	
Pressure regulating valve along with Pressure gauge	Main plant steam line for regulating the pressure	0 to 10.0 bar	0.1bar	Y	N	N	N	
Pressure	To give pressure input to PLC and HMI	0 to 5.0 bar	0.1 bar	Y	Y	Y	Y	
Temperature	To convert temperature input to 4-20 mA	0°C to + 150°C	0.1°C	Y	Y	Y	Y	
Temperature	For manual operation in case of PLC failure and indication of chamber temperature	0°C to + 150°C	0.1°C	Y	Y	Y	-	

6.5 Batch data display and record printing

Batch report should be in the mode of dot matrix online printing and strip chart recording. HMI should be able to store minimum of 1 cycle & provision for connecting with PC.

HMI size should not be less than 5.5 inches and it should be colour display with touch screen.

The HMI display should include the following important parameters but not limited to following:

- Process parameters (Date & Time, Batch No, Equipment ID)
- Alarm event
- Event log
- Process value display
- F_0 value

The printer should include the following important parameters but not limited to following:

Specifications	Remarks
• Process parameters-Recipe ID • Start time and End time (cycle) • Batch No, Equipment ID and Name of the product • Name of company: HLL Biotech Limited • Name of the operator • Alarm event • Event log • Process value • F_0 value	
6.6 GMP requirements (Others)	
6.6.1 **Validation port:** a. The validation ports with tri-clamp connections and with special leak tight ferrules for insertion of 16 flexible temperature sensors (Vendor to provide the Thermocouple entry gland using finger plate assembly for all sterilizers) b. There must be one sanitary port complete with sanitary blank, for validation thermocouples. The port should be located on one side of chamber in an easily accessible location (Size: 2" OD) c. The sanitary port should have validation connections for thermocouples (Size: 2" OD). d. There should be a Tri clamp at the drain near the filter housing (downstream) (Size: 1" OD). e. There should be a sanitary Tri-clamp type port in the drain piping, immediately adjacent to the drain temperature monitor, for installation of validation monitoring probe(Size: 1" OD)	
6.6.2 Automatic F_0 value calculation for each temperature monitoring location.	
6.6.3 Standard door interlocking function during sterilization cycle and at the end. a. Both doors should not open at a time. b. During the operation of the cycle the door should not open c. After completion of sterilization cycle, both loading and unloading side doors should not open until acknowledgement from operator. d. After the confirmation for unloading completion by the operator from the unloading side, the door from the loading side should open. e. The door should not open with over pressure inside the chamber.	
6.6.4 Vacuum pump to be provided with the system. The vacuum system should be able to evacuate the chamber up to a pressure of 40 mbar within 10 minutes (chamber clean, dry and empty) and maintaining the vacuum. The autoclave should be capable of obtaining any vacuum between atmospheric pressure and 40 mbar. The rate of change of pressure when vacuum is pulled should be adjustable.	
6.6.5 Vacuum break filter: 0.22 µm Code 7 type filter cartridges with arrangements for in-situ sterilization and provision for in-situ integrity connectors to be provided. This filter housing TC end to extended till unloading side for pressure equalization after vacuum creation. Provision	

	Specifications	Remarks
	for connecting disposable capsule filter to be provided at the unloading side.	
6.6.6	Provision for air leak probe as per HTM 2010	
6.6.7	Jacket to be provided with steam trap.	
6.6.8	Sampling valve in the steam inlet line for collection of steam sample.	
6.6.9	For easy & safety operation vendor should provide the condenser in the steam sample valve outlet	
6.6.10	Sampling valve in the condensate drain line for collection of condensate sample.	
6.6.11	Vendor to give code numbers for each component. Name tag of the components should be of SS plates & it should be tied with SS rope.	
6.6.12	Equipment, valves, and instrumentation should be uniquely identified in accordance with a standard numbering and location system. The system will be agreed between Vendor and Client at the time of order.	
6.6.13	SS panel to be flushed appropriately to the wall /ceiling/floor/LAF accordingly to avoid any dead space along with the coving on all the sides and corners.	
6.6.14	All valves and instruments are to be physically tagged /labeled with their equipment numbers.	
6.6.15	All the valves with in the sterile boundary must be of diaphragm valve.	
6.7	**Specific requirements**	
6.7.1	Indication of chamber pressure by pressure gauge and visual LED for door open/ close mounted on loading side and unloading side	
6.7.2	Door type for autoclaves as follows :	

Area	Equipment code	Door Type
MBB block – Hep B	B1-SAT-01	Double door with horizontal sliding
MBB block – Hep B	B1-SAT-02	
MBB block – Hib	B1-SAT-03	
BCG Bulk and Formulation block	F4-SAT-01	
BCG Bulk and Formulation block	F4-SAT-02	

6.7.3	Fully automatic PLC based operation.				
6.7.4	Control Panel should be placed in the loading side of the autoclave.				

	Specifications	Remarks
6.7.5	Arrangement of alternative power supply (UPS) to control and monitoring system.	
6.7.6	All utility points will be provided nearer to the equipment. Hooking up of the equipment to the nearest utility points will be in the vendor's scope.	
6.7.7	Pressure relief valve should be provided for safety purposes	
6.7.8	Automatic F_0 value calculation for each temperature monitoring port	
6.7.9	The chamber floor should be on the same plane with the floor of the trolley, so that the loading carriage can directly be moved into the chamber	
6.7.10	The trolley should carry two different carriages at a time and the chamber should also accommodate two carriages.	
6.7.11	**Sterilization Chamber:** The chamber should be rectangular, with smooth and rounded corners. The chamber should be designed as per ASME pressure vessel code. The chamber should be made of SS316L with surface roughness less than 0.6µm. The chamber should be re-inforced with an SS 304 jacket. The sterilizer support frame for the entire structure should be made of SS 304. The sterilizer should be able to reach and maintain sterilization temperature of 121°C- 134°C. The temperature should be settable parameter.	
6.7.12	**Chamber Doors:** Steam Sterilizers should have sliding double door with automatic closing and opening. The door should be made of SS 316L with internal surface roughness less than 0.6µm. The door gaskets should be made of high temperature resistant silicone rubber with rounded corners	
6.7.13	**Door Safety** The following door safety features should be provided for operator safety: • Door interlocking to prevent simultaneous opening of both the doors. • Door process lock to prevent opening of doors when the process is ON • Door obstructive sensor to be provided	
6.7.14	**FAT/SAT the following need to be demonstrated :** a. All probes to reach 121 ^{0}C within 30 sec of the first probe for above 800L capacity chamber and 15 sec for below 800 L Chamber capacity. b. Temperature differences between any two probes should not be more than 1 ^{0}C during hold time. c. Temperature Recorders should have accuracy of at least 1% over range 50 ^{0}C to 150 ^{0}C. d. Pressure recorders should have accuracy of ±1.6 % over the range of 1 bar to 3 bar. e. Pressure recorders should have an accuracy of at least 0.01 bar. f. Temperature variation during sterilization hold time should not be more than 1 ^{0}C	
6.7.15	Vendor to perform empty chamber validation during SAT	

Specifications	Remarks

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Multiple Bacterial Bulk block and BCG bulk & Formulation block** of **Integrated Vaccines Complex, at Chengalpattu**

The equipment location is indicated in the relevant block of the layout enclosed as URS **Annex-1.**

Block Name	Equipment Code	Loading Room No.	Unloading Room No.
Multiple Bacterial Bulk block[HepB]	B1-SAT 01	B1G022	B1G045
Multiple Bacterial Bulk block[HepB]	B1-SAT 02	B1G022	B1G045
Multiple Bacterial Bulk block[Hib]	B1-SAT 03	B1G120	B1G137
BCG Bulk and Formulation block	F4-SAT 01	F4G034	F4G035
BCG Bulk and Formulation block	F4-SAT 02	F4G009	F4G041

7.2 Available Utility

- Electricity:_____(Report Requirement)
- Pure steam: 3 bar (Report Requirement)
- Plant Steam: 3-3.5 bar (Report Requirement)
- Chilled water/ soft water : Supply: 6-7degC, Return: 11-12deg C (or depends on process) / Amb (Report Requirement)
- Compressed air : 8-10 bar g (Report Requirement)

Note:

1. Vendor to provide Vacuum system, Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.
2. Vendor to provide the all utility consumptions in details for the equipment in the technical bid.
3. Control panel, HMI & printer should be placed in loading side of the autoclave.

8.0 ABBREVIATION

List of abbreviations

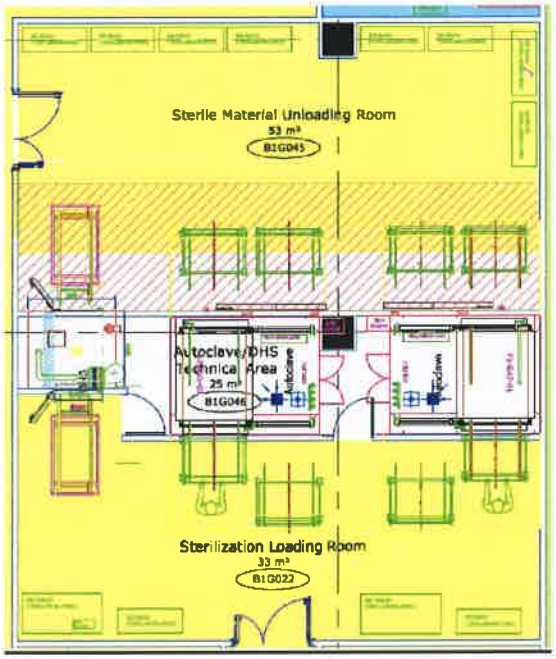
HTM	Health Technical Memorandum
ISO	International Standard Organization
HBL	HLL Biotech Limited
LAF	Laminar Air Flow
PLC	Programmable Logic Controller
NNE	Novo Nordisk Engineering
SAT	Sterilisation Autoclave
SS	Stainless steel
URS	Users Requirement Specification
HMI	Human Machine Interface

9.0 REVISION INDEX

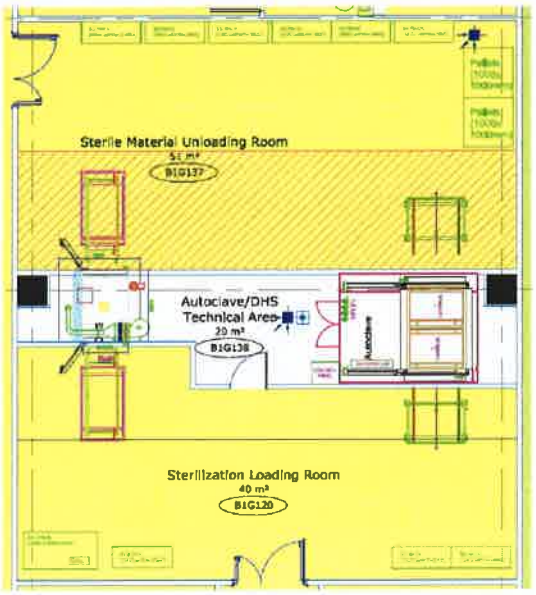
Revision	Date	Reason for revision
00	25-08-2015	First Draft for Client's Review
01	06-10-2015	Updated as per comments given by HBL dated 24-09-2015

URS Annexure-1: Layouts showing location of the Sterilization – Autoclaves (SAT)

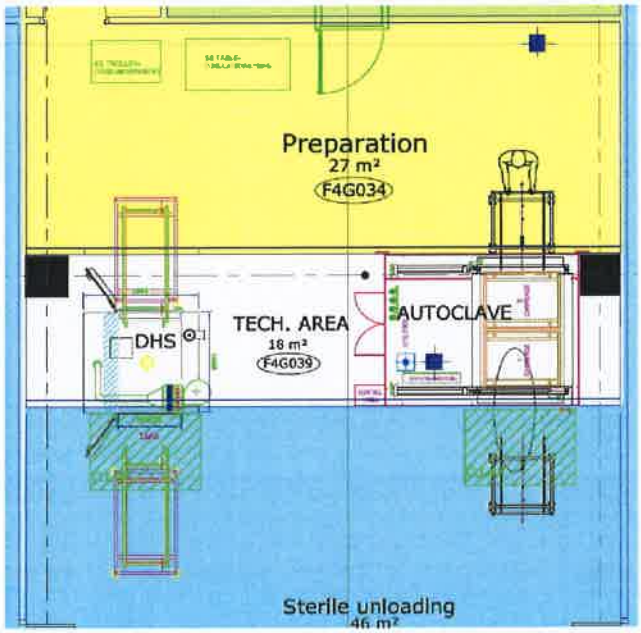
1. B1-SAT 01 and B1-SAT 02



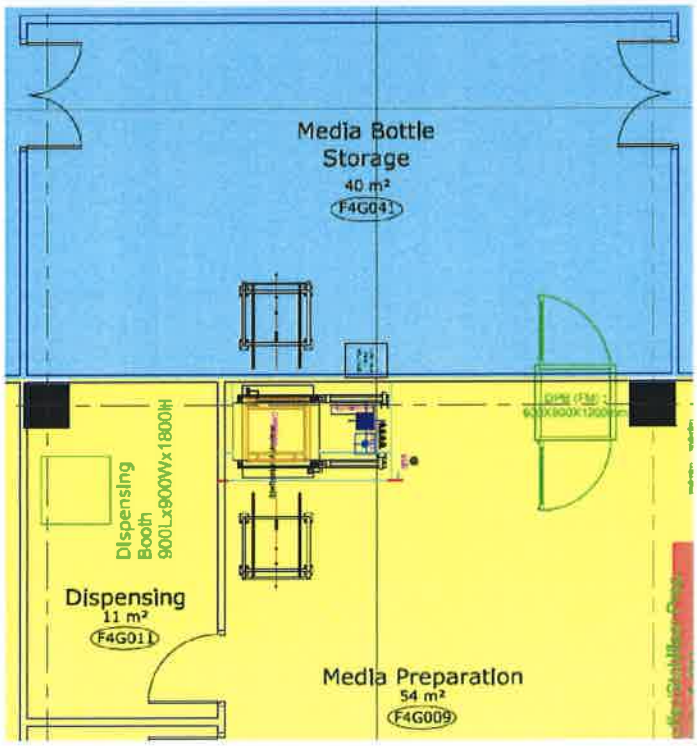
2. B1-SAT 03



3. F4-SAT 01



4. F4-SAT 02



URS Annexure 2: List of Preferred Make of Components

SL.NO	DESCRIPTION	MAKE
A	**INSTRUMENTATION**	
1.	PLC/HMI	Allen Bradley/ Siemens
2.	Operator Interface	Allen Bradley/ Siemens
3.	Temperature transmitter	Radix/ Yokogawa/ Emerson
4.	Pressure transmitter	Siemens/ Jumo/ Wika
5.	RTD sensors	Radix/ Wika/ Waaree Instruments
6.	Temperature indicator controller	Radix/ Wika/ Waaree Instruments
7.	Printer	Epson/ HP/ Canon
8.	DC source	Shavision/ Yokogawa/ Emerson
9.	Photocell sensor	P & F/ Optex/ Metler
B	**MECHANICAL**	
1.	Automatic Angle Valve	Gemu / ITT / SED
2.	Manual Ball Valve	President/ Modentic
3.	Needle Valve	President/ Modentic
4.	Safety Valve	Teleflo/Herose/ Ciprani Harrison
5.	Pressure Reducing Valve	Klinger/ Forbes Marshall/ Armstrong International
6.	Sanitary PRV	Jordon / Forbes Marshall/ Sarco
7.	Non Return Valve	Leader/ Modentic/ Alfa Laval
8.	Pressure Gauges	Forbes Marshall/ Wika/ Waaree Instruments
9.	Pressure & Vacuum Switch	Orion/ Wika/ Emerson/ Danfos
10.	Steam Trap	Spirax / ITT
11.	Vacuum Break Filter	Sartorius/ Pall/ Millipore
12.	Vacuum Pump	Newgenre / PPI
C	**PNEUMATIC**	
1.	Pneumatic door operating cylinder	Janatics/Rotex
2.	Solenoid valves for door	Janatics/ Festo
3.	Solenoid valves for Gasket	Festo/ Danfos / Janatics
4.	Solenoid valves for Process Valves	Janatics/ Festo
5.	Filter Regulator Lubricator	Janatics/ Festo
6.	Diaphragm Valve (Sterile side)	GEMU / ITT /SED
D	**ELECTRICAL**	
1.	Limit switches	Bohmen / Siemens/ Emersen
2.	Switch gear and Relays	Siemens/ L&T/ Schneider
3.	Miniature circuit breaker	Siemens/ Havells / Legrand
4.	Rotary switch	L&T/ Siemens/ Schneider
5.	Indication lamps	Technik / Mimic/ Schneider

URS Annexure 3: List of critical items to be supplied along with the package

SL.NO	DESCRIPTION	NO. OF QUANTITY
1.	Door gasket	2 set for each size
2.	Pressure switch	5 No.s
3.	Vacuum switch	5 No.s
4.	Pressure Gauge	5 No.s
5.	Compound Gauge	5 No.s
6.	Coil for Solenoid valves for doors	5 No.s
7.	Push buttons	10 No.s
8.	Coil for Solenoid valves for process	5 No.s
9.	Rotary Switch	4 No.s
10.	Indication bulb sets	10 No.s
11.	Temperature transmitter	4 Nos