User Requirement Specifications
Sterilization - Autoclave

Equipment ID:	BF-SAT 01
	BF-SAT 02

Revision index

Revision	Date	Reason for revision
00	09.12.2011	First Draft for Client's Review
01	2013.01.03	Format changed as per HLL requirement
02	2013.02.06	Client’s comment (dated 2013.01.07) incorporated
03	2013.02.20	Client’s comment (dated 2013.02.19) incorporated

URS Annexure List

URS Annex No.	Detail
1.	Layouts showing location of the Sterilisation Autoclave (BF-SAT-01) in media preparation area and (BF-SAT 02) in preparation, washing ,sterilization area
2.	List of Preferred Make of components
3.	List of recommended spares

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1.0 Approval Signature

This document is prepared by the 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

Autoclave shall be used to sterilize glass and SS items and instruments, filters and fabrics, and other items which are loaded in special baskets and/or trays.

S.No.	Identification no.	Process	Chamber inner Dimension (W x H x D in mm)
1.	BF-SAT 01	Sterilisation of Tuberlin flask (450 ml-80 nos/charge), buffer conical flask (2L-25 nos/ charge), conical flask (250 ml- 60 nos), flat bottom flasks (3 L-3- Nos)	900 x 900 x 900 mm
2.	BF-SAT 02	tubes, tuberlin flask, conical flask, flat round bottom flasks	900 x 900 x 1200 mm

Autoclave for sterilization shall have following main features:

- Operation programs for liquid, solid and porous goods

Package Unit (PU) including the following:

- Sterilizer chamber
- Supporting structure
- Integrated vacuum system
- filters for compressed 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)
- Pressure reducing valve in plant steam line
- All mating flanges/fittings, gaskets, bolts and screws for utility supplies, returns and Drain
- Instrumentation
- The unit shall be direct steam heated as well as jacket steam heated and designed for full vacuum.
- Control System with printer (able to give trends in color)
- Bioshield to seal the sterile and non-sterile areas.

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

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 a 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.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_110729_IRS_BCG_01
X.	Refer Tender document with URS; NPI/110729/EQP/TD/05

Specifications	Remarks
3.0 Process Description	
3.1 Input & Charging method	
3.1.1 The sterilizer shall be suitable for sterilization of various items such as: • Sterilization of media • Sterilisation of Tuberlin flask (450 ml-80 nos/charge), buffer conical flask (2L-25 nos/ charge), conical flask (250 ml- 60 nos), flat bottom flasks (3 L-3-Nos), • Metal parts • Filters and filter housings, • Fabrics **Note:** • Tuberlin flasks (450 ml)-dia- 120 mm, h- 100 mm • 250 ml conical flask-dia-85 mm, h- 140 mm • 2 L Buffer conical flask- dia-165 mm, h-286 mm • 3 L Flat round bottom flask- dia-185 mm, h-286 mm	
3.1.2 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 or any other better option.	
3.1.3 SS316 L loading carriage with a pair of SS316 L railing (provided inside the chamber) for smooth and easy loading. The railing should be fixed type properly welded.	
3.1.4 The chamber trolley should be provided with removable shelves for more flexibility.	
3.1.5 The chamber floor shall be on the same plane with the floor of the trolley, so that the loading carriage can directly be moved into the chamber. ***Loading level shall be defined by the vendor.***	
3.1.6 Equipment parts, garments etc. will be packed in tyvek bags before loading in the equipment for sterilization.	
3.1.7 Loading environment: • BF-SAT 01 loading will be from room of Class C (ISO 7) cleanliness zone. • BF-SAT 02 loading will be from room of class D (ISO 8) cleanliness zone	
3.2 Brief Process Steps	
3.2.1 Sterilization shall have following steps: a) Loading b) Initial Vacuum Pulsation c) Heating (Steaming) d) Hold period (Sterilization) e) Post vacuum f) Drying	

Specifications	Remarks
g) Unloading	
3.3 Output & Discharging method	
3.3.1 All sterilized articles will be unloaded from the unloading side under LAF with background Class B 3.3.2 Carriage will be taken out and articles will be unloaded from the carriage. 3.3.3 All condensates and liquids shall lead to common drain.	
4.0 Productivity Requirement	
4.1 Desired/ suggested capacity	
BF-SAT 01: Dimension of chamber of autoclave: (W X H X D): 900mm x900mm x 900 mm Chamber total volume: 729 L (approx) **BF-SAT 02:** Dimension of chamber of autoclave: (W X H X D): 900mm x900mm x 1200 mm Chamber total volume: 972 L (approx)	
4.2 Standard batch size	
Not applicable	
4.3 Change Over Time	
Not applicable	
4.4 Other Productivity Requirement	
Total sterilization cycle must not exceed 2 hours.	
5.0 Containment requirement	
Not Applicable	
6.0 GMP requirements	
6.1 Process control	
6.1.1 The equipment must operate and control the following process cycle:	
• 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 fluid cycle, the exhaust will be slow)	
• High-pressure high vacuum sterilization cycle (loading → steam/vacuum pulsing	

Specifications	Remarks
→ heat up → hold period → exhaust → vacuum drying → vacuum bleeding 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	
• Small valve set point	
• 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	
• Post pressure	
• No of post pulses	
• Exhaust on	
• Exhaust off	
• Process end pressure	
• Chamber pressure high	
• Too long time for pre vacuum	
• Too long time for heat up	

Specifications	Remarks
6.2 Failure mode detection	
The Autoclave shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1 If chamber vacuum leak test is failed	
6.2.2 If the chamber temperature overshoots	
6.2.3 If chamber temperature falls below specified level & the timer stops counting	
6.2.4 If chamber temperature falls further below specified level & the timer resets previously counted time	
6.2.5 If chamber pressure is greater than the set value	
6.2.6 Too long time for heat up	
6.2.7 Too long time for pre vacuum	
6.2.8 Too long time for post vacuum	
6.2.9 If vacuum pump trips	
6.2.10 Door pre condition fails	
6.2.11 Failure in utility supply	
a) Compressed air pressure low	
b) Plant steam pressure low	
c) Pure steam pressure low	
d) Softened water pressure low	
6.2.12 Failure in data communication	
6.2.13 Vendor shall propose detail list of alarms and interlocks in Functional specifications. The alarms and interlocks list shall be finalized with the final user during discussion of detail engineering design of the equipment	
6.2.14 Emergency stop activated	
6.2.15 Power failure	
6.2.16 Following condition need only notification to operator for procedural control	
a) UPS power low (optional)	
b) End of cycle	
c) Door opening after end of cycle	

Specifications	Remarks

6.3 In –Process control

Manual diaphragm valves to be provided as sampling valves for pure steam & chamber condensate sampling.
All necessary ports for steam quality testing as per EN 285 shall 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 5 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**
Differential pressure	Differential pressure across the sterilizing grade vacuum break filter	0 to 2000 mbar	1.0 mbar	**Y**	**Y**	**N**	**N**
Pressure	Main compressed air line for pneumatic control	0 to 10.0 bar	0.1bar	**Y**	**Y**	**N**	**N**

Specifications								Remarks
Pressure regulating valve along with Pressure gauge	Main Pure steam line for regulating the pressure	0 to 10.0 bar	0.1bar	**Y**	**Y**	**Y**	**N**	
Pressure regulating valve along with Pressure gauge	Main plant steam line for regulating the pressure	0 to 10.0 bar	0.1bar	**Y**	**Y**	**Y**	**N**	
Pressure	To give pressure input to PLC and SCR	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

Refer Installation Requirement Specification

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 sensor

b. There must be two sanitary ports complete with sanitary blank, for validation thermocouples. The port shall be located on side of chamber in an easily accessible location (Size: 2" OD)

c. The sanitary port shall have validation connections for thermocouples (Size: 2" OD).

d. There shall be a Tri clamp at the drain near the filter housing (downstream) (Size: 1" OD).

e. There shall 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)

Specifications	Remarks
6.6.2 Automatic F0 value calculation for each temperature monitoring location.	
6.6.3 Standard door interlocking function during sterilization cycle and at the end. • Both doors shall not be opened at a time. • During the running cycle the door shall not open • After sterilization completion the loading side door shall not be opened. • After the command for unloading completion by the operator from the sterile side, the door from loading side can be opened. • The door shall not open with over pressure inside the chamber.	
6.6.4 Temperature trend chart recording and printing software to be provided.	
6.6.5 Vacuum pump to be provided with the system.	
6.6.6 Vacuum bleed filter: hydrophobic with arrangements for in place sterilization and provision for in-place integrity test.	
6.6.7 Provision for air leak probe as per HTM 2010	
6.6.8 Jacket to be provided with steam trap.	
6.6.9 Sampling valve in the steam inlet line for collection of steam sample.	
6.6.10 For easy & safety operation vendor shall provide the condenser in the steam sample valve outlet	
6.6.11 Sampling valve in the condensate drain line for collection of condensate sample.	
6.6.12 Vendor to give code numbers for each component.	
6.6.13 Equipment, valves, and instrumentation shall 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.	
6.6.14 All valves and instruments are to be physically labeled with their equipment numbers	
6.6.15 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	
6.7 Specific requirements	
6.7.1 Indication of chamber pressure by pressure gauge and visual LED for door open/ close mounted on both non-sterile and sterile side	
6.7.2 The chamber floor shall be on the same plane with the floor of the trolley, so that the loading carriage can directly be moved into the chamber	
6.7.3 The trolley should carry two different carriages at a time and the chamber shall also	

Specifications	Remarks
accommodate two carriages.	
6.7.4 **Sterilization Chamber:** The chamber shall be rectangular, with smooth and rounded corners. The chamber shall be designed as per ASME pressure vessel code. The chamber shall be made of SS316L with surface roughness less than 0.5µm. The chamber shall be re-inforced with an SS 304 jacket. The sterilizer support frame for the entire structure shall be made of SS 304. The sterilizer shall be able to reach and maintain sterilization temperature of 121°+ 2°C. The temperature shall be settable parameter.	
6.7.5 **Chamber Doors:** Steam Sterilizers shall have horizontal sliding double door with automatic closing and opening. The door shall be made of SS 316L with internal surface roughness less than 0.8µm. The door gaskets shall be made of high temperature resistant silicone rubber with rounded corners	
6.7.6 **Door Safety** The following door safety features shall 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	
6.7.7 **Validation port:** The chamber shall be provided with two validation ports with tri-clamp connections and with special leak tight ferrules for insertion of 16 flexible temperature sensor	
6.7.8 **Vacuum Break Filter:** A 0.2-micron vacuum break filter shall be provided on the sterile side for pressure equalization after vacuum creation	
6.7.9 Double door with horizontal sliding and chamber shall be horizontal type.	
6.7.10 The chamber trolleys should be provided with removable shelves for more flexibility if required. The trolley shall be 2 in numbers. The top frame is on four heavy studs for level adjustment. The rails on the top frame match with the rails in the chambers. The trolley is also provided with two fixed and two swiveling castor wheels	
6.7.11 Fully automatic PLC/ PC based operation. Preferred make of PLC is Allan Bradley/ Siemens	
6.7.12 Arrangement of alternative power supply (UPS) to control and monitoring system.	
6.7.13 The Vendor shall ensure maintenance parts availability for a minimum of 15 months from delivery.	

Specifications	Remarks
6.7.14 Cables, air tubes, etc required from the point (single utility point) to equipment is in scope of vendor	
6.7.15 Analogue module with back up	
6.7.16 Automatic F0 value calculation for each temperature monitoring port	
6.7.17 Vendor shall install the emergency stop function on both Loading and unloading side of the sterilization autoclave	
6.7.18 Vendors have to ensure the better data restoration for both batch data recording and alarm printing. Temperature trend chart recording and printing software to be provided.	
6.7.19 Maintenance and utility shall be on one side only.	
6.7.20 Connection to drains shall be in vendor scope.	
6.7.21 If technical area is less, then there shall be a provision to remove the control panel from the machine and keep it on side wall. So that the maintenance area will increase.	
6.7.22 Equipment should be flushed with wall on both non-sterile and sterile side with bio seal.	
7.0 Constraints	
7.1 Equipment location and available space	
This equipment will be installed in **the Revival of BCG vaccine manufacturing facility, BCGVL, Guindy, Chennai** area as follows. **Equipment Location:** Floor: First Floor - Bulk Plant: Revival of BCG Vaccine Laboratory, Guindy, Chennai The equipment location is indicated in the relevant block of the layout enclosed as URS Annex-1. **For BF-SAT 01** **Physical condition of the rooms:** Media preparation (BF016) Room dimension: 45.1 m^2 Room Height: 3000 mm 1. Room will be non-hazardous 2. Class: EU Class “C” 3. Differential Pressure: 30Pa Absolute 4. Temperature maintained: 22°C ±2°C 5. Relative Humidity: < 55% RH	

Specifications	Remarks
Media bottle storage (BF033) Room dimension: 28.4 m^2 Room Height: 3000 mm Technical area: 1080 x 3110 mm 1. Room will be non-hazardous 2. Class: EU Class “B” 3. Differential Pressure: 45Pa Absolute 4. Temperature maintained: 22°C ±2°C 5. Relative Humidity: < 55% RH **For BF-SAT 02** **Physical condition of the rooms:** Preparation (BF050) Room dimension: 29.71 m^2 Room Height: 3000 mm 1. Room will be non-hazardous 2. Class: EU Class “D” 3. Differential Pressure: 25Pa Absolute 4. Temperature maintained: 22°C ±2°C 5. Relative Humidity: < 55% RH Media bottle storage (BF034) Room dimension: 24.90 m^2 Room Height: 3000 mm Technical area: 1080 x 5485 mm 1. Room will be non-hazardous 2. Class: EU Class “B” 3. Differential Pressure: 45Pa Absolute 4. Temperature maintained: 22°C ±2°C 5. Relative Humidity: < 55% RH	
7.2 Utility Requirement	
➢ Electricity: 6 kW (For each Autoclave)(Report Requirement) ➢ Pure steam: 3 bar (Report Requirement) ➢ Plant Steam: 3-3.5 bars (Report Requirement) ➢ Chilled water/ soft water: Supply: 6-7degC, Return: 11-12deg C/ 3-4 bar , Ambient (Report Requirement) ➢ Compressed air / nitrogen pressure 6 bar g (Report Requirement) ***Note: Vacuum system to be supplied by the Vendor*** **The vendor should plan accordingly for any change**	

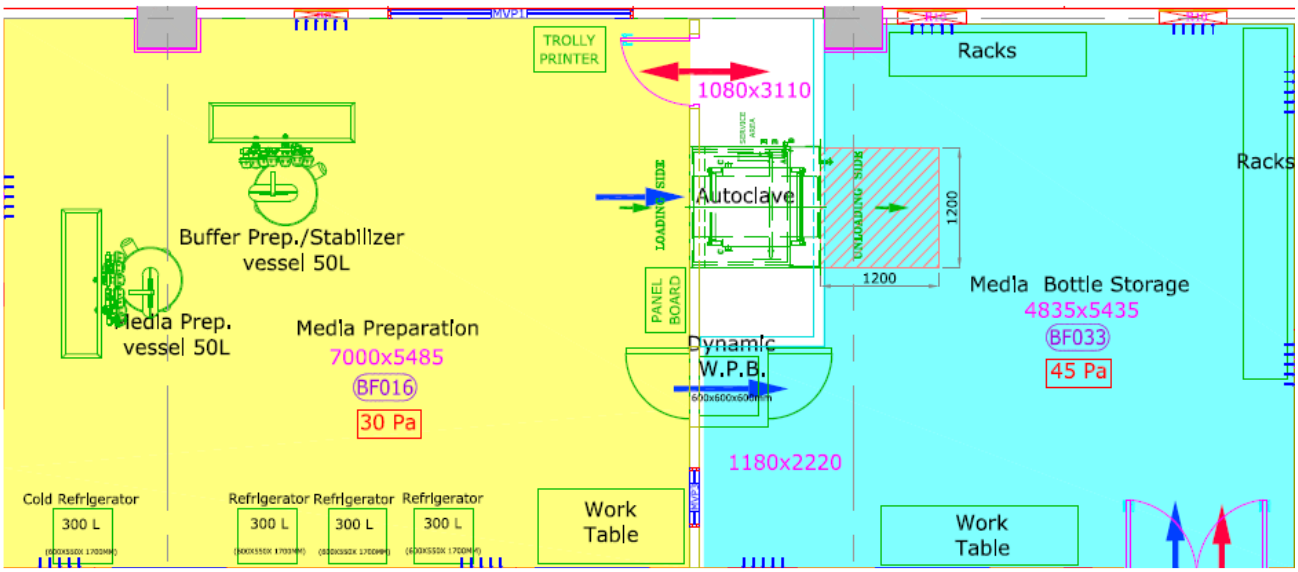
8.0 Abbreviation

List of abbreviations

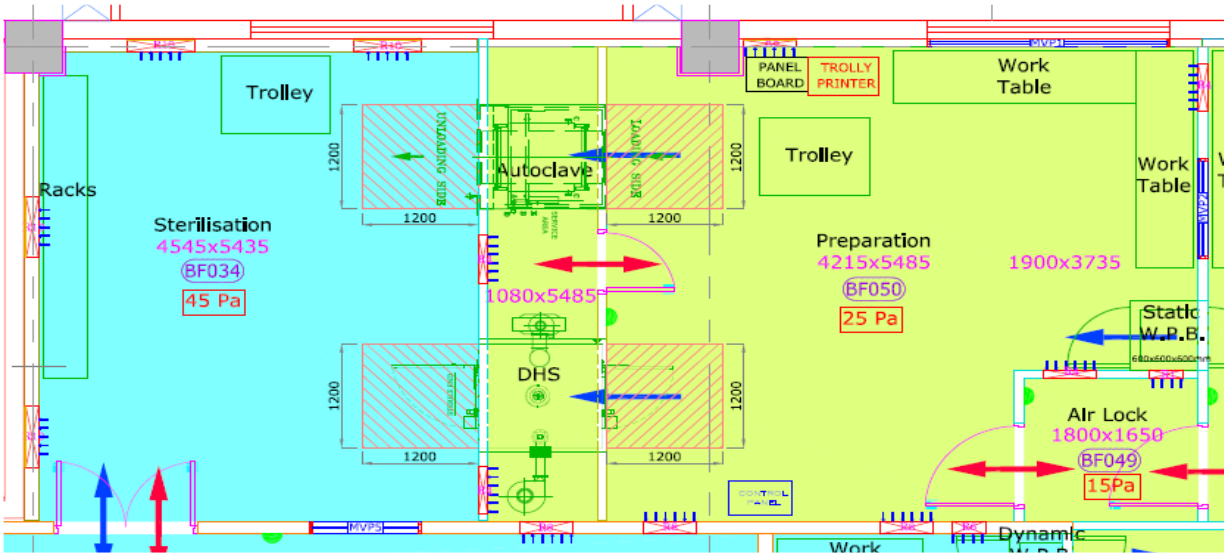
HTM	Health Technical Memorandum
ISO	International Standard Organisation
LAF	Laminar Air Flow
PLC	Programmable Logic Controller
NNE	Novo Nordisk Engineering
SAT	Sterilisation Autoclave
SS	Stainless steel
URS	Users requirement specification

URS Annexure 1: LAYOUT POSITION

BF-SAT 01
BF016 (Loading side) &BF033 (Unloading Side)



BF-SAT 02
BF050 (Loading side) & BF034 (Unloading Side)



URS Annexure 2: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
A	**INSTRUMENTATION**	
1.	PLC	Mitsubishi/ Allen Bradley/ Siemens
2.	Operator Interface	Mitsubishi/ 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	Crane/ Saunder/ Gemu
2.	Manual Ball Valve	President/ Modentic/ Fluidine
3.	Needle Valve	President/ Modentic/ Fluidine
4.	Safety Valve	Teleflo/Herose/ Ciprani Harrison
5.	Non Return Valve	Leader/ Modentic/ Alfa Laval
6.	Pressure regulating valve	Klinger/ Forbes Marshall/ Armstrong International
7.	Gauges	Forbes Marshall/ Wika/ Waaree Instruments
8.	Pressure & Vacuum Switch	Orion/ Wika/ Emerson
9.	Level Switch	Mahalaxmi/ Endress & Hauser/ Emerson
10.	Steam Trap	Spirax/ Steriflow/ ITT

SL.NO	DESCRIPTION	MAKE
11.	Vacuum Break Filter	Sartorius/ Pall/ Millipore
12.	Vacuum Pump	Newgenre/PPI/ Falcon Pumps
C	**PNEUMATIC**	
1.	Pneumatic door operating cylinder	Janatics/Rotex/ Parker
2.	Solenoid valves for door	Janatics/ Festo/ Parker
3.	Solenoid valves for Gasket	Patcon/ Festo/ Danfoss
4.	Solenoid valves for Process Valves	Janatics/ Festo/ Emerson
5.	Filter Regulator Lubricator	Janatics/ Festo/ Ingersoll
D	**ELECTRICAL**	
1.	Control Panel	Allen Bradley/Siemens/ ABB
2.	Limit switches	Bohmen/Siemens/ Emersen
3.	Switch gear and Relays	Siemens/ L&T/ Schneider
4.	Miniature circuit breaker	Siemens/ Havells/ Legrand
5.	Rotary switch	L&T/ Siemens/ Schneider
6.	Indication lamps	Technik / Mimic/ Schneider

URS Annexure 3: List of recommended spares

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