User Requirement Specifications
Decontamination - Autoclave

Block Code	Area	Identification #	Qty (Nos)	Internal Chamber Dimensions (W x H x D) in mm	Door type
R1	Measles and Rubella Bulk Block-Measles	R1-DAT-01	01	900 x 900 x 1200	Double door with horizontal sliding
R1	Measles and Rubella Bulk Block-Rubella	R1-DAT-02	01		

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nne pharmaplan	User Requirement Specifications				HBL
	Equipment/System	Decontamination Autoclave			
	Identification #	-	Document #	URS/DAT 03	
	Effective Date	02/11/15	Revision#	00	

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 decontamination should have following main features:

- Operation programs for materials (liquid & solids) and garments.

Package Unit (PU) including the following:

- Autoclave chamber
- Supporting structure
- Integrated vacuum system
- Filters for process air and for exhaust air
- Piping (valves, safety devices, filters, steam traps, pipes, fittings, etc.)
- 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
- 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**
  - Sl.NO 5 CE Conformity,
  - Sl.NO 7 ANSI/NSF 49-2008
  - Sl.NO 8 ISO 14664
  - Sl.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 autoclave should be suitable for decontamination of : • Glass containers • SS containers / SS cage / racks • Liquid media in glass • Silicon tubings , Gaskets and siphon sets • Disposable syringes / Needle /Gloves • Clean room garments • Machine components	
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 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.***	
3.1.6 Equipment parts, garments etc. will be packed in sterilizable bags before loading in the equipment for sterilization.	
3.2 Brief Process Steps	
Decontamination should have following steps 1. Loading 2. Initial Vacuum Pulsation 3. Heating (Steaming) 4. Hold period (Decontamination) 5. Post vacuum 6. Drying 7. Unloading	

3.3 Output & Discharging method

3.3.1 Articles will be unloaded from unloading side. Reusable articles should be unloaded in a class D room and taken into wash area by carriage for preparation.

3.3.2 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 without cooling.

3.3.4 All condensates and liquids from the chamber should lead to the kill tank without cooling.

4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity

Decontamination – Autoclave (DAT):

Sl. No	Area	Identification #	Internal Chamber Dimensions (W x H x D) in mm	Qty (Nos)
1	Measles and Rubella Bulk Block-Measles	R1-DAT-01	900 x 900 x 1200	01
2	Measles and Rubella Bulk Block-Rubella	R1-DAT-02	900 x 900 x 1200	01

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 decontamination 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:

- Vacuum leak test cycle (As per HTM 2010)
- Bowie Dick cycle (17 min at 121 °C and 3.5 min at 135 °C)
- Standard decontamination cycle (loading → steaming → hold period→ slow/fast exhaust

• Standard cycle 1- Liquid (123°C)	
• Standard cycle 2 -Fabric (134 °C)	
• Temperature uniformity within the chamber, as shown by the distribution temperature sensors, must be less than ± 1.0 °C of the mean chamber temperature (mean of the distribution temperature sensors) after one minute in the dwell period.	
• High-pressure high vacuum decontamination cycle (loading → steam/vacuum pulsing → heat up → hold period → exhaust → vacuum drying → vacuum break by 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	
• Decontamination hold temperature	
• Decontamination hold time	
• Temperature control band	
• Overshoot temperature	
• Decontamination stop temperature	
• Decontamination reset temperature	
• Post vacuum start pressure	
• Post vacuum	
• Post vacuum hold time	
• Vacuum break	
• 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	
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 to be provided as sampling valves for 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 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
Time	Decontamination time	On real time basis	1 Sec	Y	Y	Y	Y
Pressure	Chamber pressure	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 vacuum break filter	0 to 2000 mbar	1.0 mbar	Y	N	N	N
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 plant steam line for regulating the	0 to 10.0 bar	0.1bar	Y	Y	Y	N

	pressure							

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 the 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 the following:

- 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 decontamination cycle and at the end. a. Both doors should not be opened at a time. b. During the operation cycle the door should not open. c. After completion of decontamination 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 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 should be provided on the loading side for pressure equalization after vacuum creation	
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 Sampling valve in the condensate drain line for collection of condensate sample.	
6.6.10 For easy & safety operation vendor should provide the condenser in the steam sample valve outlet	
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 All valves and instruments are to be physically tagged / labeled with their equipment numbers	
6.6.14 SS panel to be flushed appropriately to the wall /ceiling/floor accordingly to avoid any dead space along with the coving on all the sides and corners	
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 both loading and unloading side

6.7.2 Door type for autoclaves as follows :

Area	Equipment code	Door Type
Measles and Rubella Bulk Block- Measles	R1-DAT-01	**Double door with horizontal sliding**
Measles and Rubella Bulk Block- Rubella	R1-DAT-02	

6.7.3 Fully automatic PLC/ PC based operation.

6.7.4 Control Panel should be placed in the unloading side of the autoclave.

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 equipments to the nearest utility points will be in the vendor's scope.

6.7.7 Automatic F_0 value calculation for each temperature monitoring port

6.7.8 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

6.7.9 The trolley should carry two different carriages at a time and the chamber should also accommodate two carriages.

6.7.10 **Decontamination 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 0.5µm. The chamber should be re-inforced with an SS 304 jacket. The autoclave support frame for the entire structure should be made of SS 304.

The autoclave should be able to reach and maintain decontamination temperature of 121°C to 134°C. The temperature should be settable parameter.

6.7.11 **Chamber Doors:**

Steam Autoclaves should have sliding double door with automatic closing and opening. The door should be made of SS 316L with internal surface roughness less than 0.8µm.

The door gaskets should be made of high temperature resistant silicone rubber with

rounded corners

6.7.12 **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.

6.7.13 The drain from chamber and drain from vacuum ring pump , both should be connected to biowaste drain.

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 The steam condensate received inside the chamber during initial pulsing of steam before start-up of decontamination cycle should not get drained from the autoclave chamber without completion of decontamination cycle. Provision should be provided to accommodate the condensate inside the chamber itself.

7.0 CONSTRAINTS

7.1 Equipment location and available space

These equipment will be installed in the **Measles and Rubella Bulk Block** of **Integrated Vaccines Complex, at Chengalpattu**

Block Name	Identification #	Loading Room No.	Unloading Room No.
Measles and Rubella Bulk Block- Measles	R1-DAT-01	R1G062	R1G063
Measles and Rubella Bulk Block- Rubella	R1-DAT-02	R1G094	R1G095

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

7.2 Available Utility

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

Note: Vendor to provide Vacuum system, Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.

Vendor to provide the all utility consumptions in details for the equipment in the technical bid.

8.0 ABBREVIATION

List of abbreviations

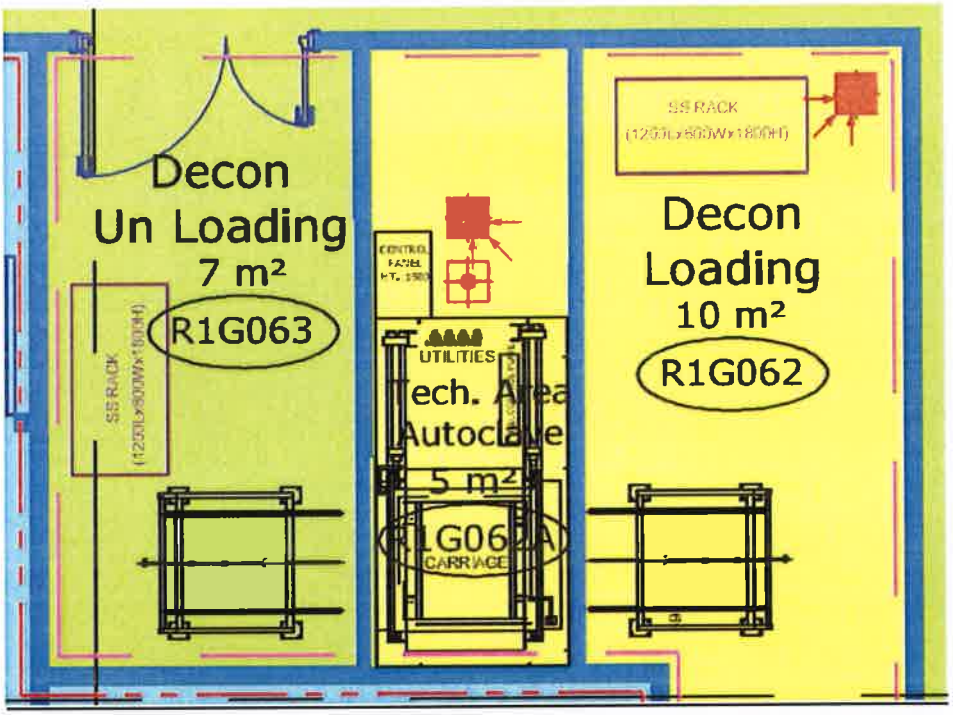
HTM	Health Technical Memorandum
ISO	International Standard Organisation
HBL	HLL Biotech Limited
PLC	Programmable Logic Controller
NNE	Novo Nordisk Engineering
DAT	Decontamination Autoclave
SS	Stainless steel
URS	Users requirement specification

9.0 REVISION INDEX

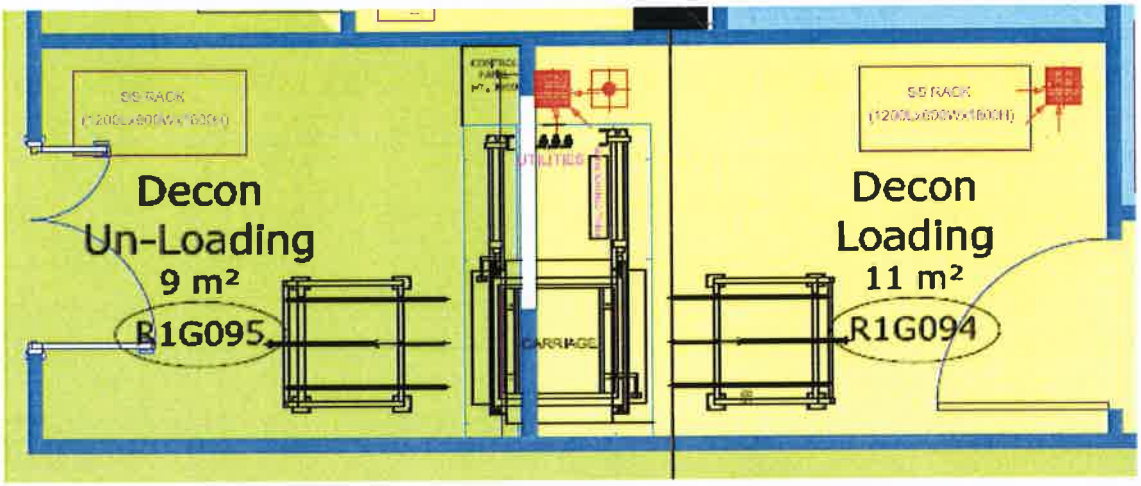
Revision	Date	Reason for revision
00	27-10-2015	First Draft for Client's Review

URS Annexure-1: Layouts showing location of the Decontamination – Autoclaves (DAT)

1. R1-DAT-01



2. R1-DAT-02



URS Annexure 2: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
A	**INSTRUMENTATION**	
1.	PLC	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/ Fluidine
3.	Needle Valve	President/ Modentic/ Fluidine
4.	Safety Valve	Teleflo/Herose/ Ciprani Harrison
5.	Sanitary PRV	Jordon / Forbes Marshall / Sarco
6.	Non Return Valve	Leader/ Modentic/ Alfa Laval
7.	Pressure regulating valve	Klinger/ Forbes Marshall/ Armstrong International
8.	Pressure Gauges	Forbes Marshall/ Wika/ Waaree Instruments
9.	Pressure & Vacuum Switch	Orion/ Wika/ Emerson / Danfoss
10.	Steam Trap	Spirax/ Steriflow/ ITT
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	Festo/ Danfoss / Janatics
4.	Solenoid valves for Process Valves	Janatics/ Festo/ Emerson
5.	Filter Regulator Lubricator	Janatics/ Festo/ Ingersoll
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