

HLL LIFECARE LIMITED, CHENNAI

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR

nne pharmaplan®

User Requirement Specifications

**Equipment/System**

Decontamination - Autoclave

Identification

Q-DAT01

Document

URS/Q-DAT 01

Effective Date

2013-06-24

Revision

03

User Requirement Specifications Decontamination - Autoclave

Process Code	Area	Equipment code	Qty(Nos)	Capacity
Q	STERILITY MEDIA, MICROBIOLOGY	Q-DAT01	1	(W x D x H) 600 x 900 x 600 (mm)

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URS Annexure List

URS Annex No.	Detail
1.	Layouts showing location of the Decontamination Autoclave in Sterility media, Microbiology bulk decontamination area
2.	List of Preferred Make of components

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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 Vaccine 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 and authorized by the appropriate Project Authority.

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2.0 OVERVIEW

Autoclave shall be used to decontaminate various items that come in contact with organisms and material according to Biosafety class 2.

Sl.No	Identification no.	Area Specification	Process	Chamber inner Dimension (W x D x H in mm)
1.	Q-DAT 01	Decontamination area	<p>To decontaminate minimum 200 bottles (100 ml)/shift.</p> <p>Dimensions of 200 ml rectangular bottle: (H-150mm, B-60mm, L-50mm)</p> <p>Note: Multiple sterilization cycles need to be considered for Petri dishes, flasks.</p>	600 x 900 x 600 mm


- Operation programs for liquid, solid and porous goods and biohazard waste.
- Package Unit 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 plant steam line
 - All mating flanges/fittings, gaskets, bolts and screws for utility supplies, returns and drain
 - Instrumentation
 - Control System with printer for batch report and color trend printing
 - 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

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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. In 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 an 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 vendor's 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/05

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Specifications	Remarks
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3.0 PROCESS DESCRIPTION

3.1 Input & Charging method

3.1.1	The autoclave shall be suitable for decontamination of : <ul style="list-style-type: none"> To decontaminate minimum 200 bottles (100 ml)/ cycle, Petri dishes, flasks per shift Note: Dimensions of 200 ml rectangular bottle: height 150 mm, breadth 60 mm, length 50 mm 	
3.1.2	Articles for decontamination will be loaded manually in the autoclave so that all articles can come in contact of the steam using movable/ rotary carriage or any other better option.	
3.1.3	SS316L loading carriage with a pair of SS316L railing (provided inside the chamber) for smooth and easy loading. The railing should be fixed type properly welded.	
3.1.4	The chamber carriage should be provided with removable shelves for more flexibility and carriage floor trolley MOC shall be of SS304.	
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	Material will be packed in tyvek bags before loading in the equipment for decontamination.	
3.1.7	Loading environment for Q-DAT01 : loading will be from room Class C (ISO 7) cleanliness zone	

3.2 Brief Process Steps

Decontamination shall 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. Articles that can be reusable shall be unloaded in a class D room and taken into wash area by carriage for preparation and another round of sterilization	
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 without cooling.	
3.3.4	All condensates and liquids from the chamber shall lead to the kill tank without cooling.	


4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity

Dimension (W X D X H) of autoclave chamber:


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Q-DAT 01: 600mm x 900mm x 600 mm					
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:					
• 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					
• Liquid cycle					
• Sterilization of the vent filter					
• High-pressure high vacuum decontamination cycle (loading → steam/vacuum pulsing → heat up → hold period → exhaust → vacuum drying → vacuum bleeding 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					
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• heat up control band	
• Small valve set point	
• 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	
• 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	

6.2 Failure mode detection

6.2.1	The Autoclave shall 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	

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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) Softened water pressure low

6.2.1.12 Failure in data communication

6.2.1.13 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

6.2.1.14 Emergency stop activated

6.2.1.15 Power failure

6.2.1.16 Following condition need only notification to operator for procedural control

a) UPS power low

b) End of cycle

c) Door opening after end of cycle

6.3 In –Process control

Manual diaphragm valves to be provided as sampling valves for steam & chamber condensate sampling.
Manual ball valve for side pocket & recirculation sampling valve
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 temperatur e	0°C to + 150°C	0.1 °C	Y	Y	N	Y
Temperature	Chamber condensat e drain	0°C to + 150°C	0.1 °C	Y	Y	Y	Y

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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 pressure	0 to 10.0 bar	0.1bar	Y	Y	Y	N

6.5 Batch data display and record printing

Refer Installation Requirement Specification


Batch report should not be in strip chart recording ie. online printing is desired with minimum storage of 10 cycles. After the cycle completion the batch report and as well as trend print out should be in different colours.

6.6 GMP requirements (Others)

6.6.1	Minimum 2-validation port for inserting at least 16 probes through each port during validation.	
6.6.2	Automatic F0 value calculation for each temperature monitoring location.	
6.6.3	Standard door interlocking function during decontamination cycle and at the end. <ul style="list-style-type: none"> Both doors shall not be opened at a time. During the running cycle the door shall not open After decontamination completion the loading side door shall not be opened. 	

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- After the command for unloading completion by the operator from the unloading side, the door from loading side can be opened.

6.6.4 Temperature trend chart recording and printing software to be provided with minimum storage of 10 cycles.

6.6.5 Vacuum pump to be provided with the system.

6.6.6 Vacuum bleed filter: hydrophobic with arrangements for in place decontamination 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 Sampling valve in the condensate drain line for collection of condensate sample.

6.6.11 For easy & safety operation vendor shall provide the condenser in the steam sample valve outlet

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

6.6.16 All the valves at sterile side must be 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 For **Q-DAT 01 Double door with Hinged (standard) sliding**

6.7.3 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.


6.7.4 Fully automatic PLC/ PC based operation.

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.

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6.7.7 Analogue module with back up	
6.7.8 Automatic F0 value calculation for each temperature monitoring port	
6.7.9 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	
6.7.10 The trolley should carry two different carriages at a time and the chamber shall also accommodate two carriages.	
6.7.11 Decontamination 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 autoclave shall be able to reach and maintain decontamination temperature of 121 °C to 134 °C. The temperature shall be settable parameter.	
6.7.12 Chamber Doors: Steam Autoclaves shall have 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	
6.7.13 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 Door obstructive sensor to be provided.	
6.7.14 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	
6.7.15 Vacuum Break Filter: A 0.2-micron vacuum break filter shall be provided on the unloading side for pressure equalization after vacuum creation	
6.7.16 Vendor shall install the emergency stop function on both Loading and unloading side of the decontamination autoclave	
6.7.17 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.	
6.7.18 Maintenance and utility shall be on one side only.	
6.7.19 Connection to drains shall be in vendor scope.	

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6.7.20 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.

6.7.21 Equipment should be flushed with wall on both loading and unloading side with bio seal.

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

6.7.23 During FAT/SAT the following need to be demonstrated:

- All probes to reach $121^{\circ}\text{C} \pm 3^{\circ}\text{C}$ within 30 sec of the first probe for above 800L capacity chamber and 15 sec for below 800 L Chamber capacity.
- Not more than 2°C difference between any two probes during hold time.
- Temperature Recorders shall have accuracy of at least 1% over range 50°C to 150°C .
- Pressure recorders shall have accuracy of $\pm 1.6\%$ over the range of 1 bar to 3 bar.
- Pressure recorders shall have an accuracy of at least 0.01 bar.

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in **DPT vaccine manufacturing Facility at PII, Coonor.**

Equipment Location: Decontamination- Autoclave (M1G013A)

Floor: Ground Floor –Sterility media, Microbiology Block

Class: EU Class General

Room dimension: (1140 X 3800) mm

Room height: 5.5 m

False ceiling height: 3 m

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

Physical condition of the rooms:

Decontamination(M1G014)


- Room will be non BSL
- Class: EU Class “C”
- Differential Pressure: 20 Pa Absolute
- Temperature maintained: $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Relative Humidity: < 55 % RH

Unloading room (M1G013)

- Room will be non-hazardous
- Class: EU Class “D”
- Differential Pressure: 10 Pa Absolute
- Temperature maintained: $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Relative Humidity: < 55 % RH

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7.2 Available utility

- Electricity: _____ (Report Requirement)
- Plant steam: 3-3.5 bar (Report Requirement)
- Chilled water/ Softened water: Supply: 6-7degC, Return: 11-12deg C (or depends on process) / Amb (Report Requirement)
- Compressed air / nitrogen pressure: 8-10 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
DAT	Decontamination Autoclave
SS	Stainless steel
URS	Users requirement specification

REVISION INDEX

Revision	Date	Reason for revision
00	2012-09-12	First Draft
01	2013-03-25	Format changed as per HLL requirement
02	2013-06-04	As per the MOM dtd 09-04-2013 and 10-04-2013 with HLL/ PIIC
03	2013-06-24	As per the comments from HLL by email dtd:2013-06-17

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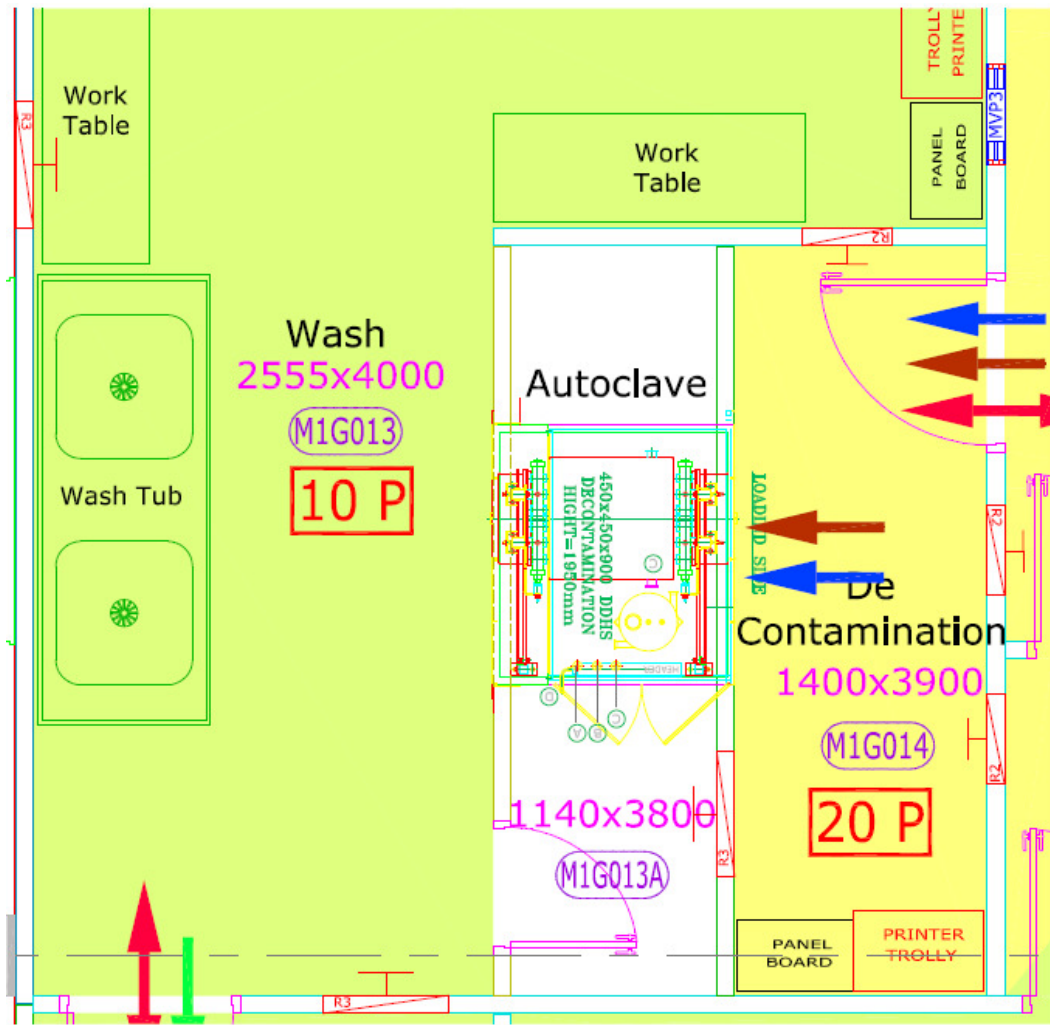
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URS Annexure 1 LAYOUT POSITION

Room for Q-DAT 01:

Loading side (M1G014) and unloading side (M1G013)



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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	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.	Pressure 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

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2013-06-24

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03

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.	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