

nne pharmaplan®

User Requirement Specifications

Equipment/System

Autoclave cum Bung Processor

Identification

F-ABP 01

Document

URS/F-ABP 01

Effective Date

2013-10-07

Revision

04



User Requirement Specifications

Autoclave cum Bung Processor

Process Code	Area	Process Code	Equipment code
F	Formulation	F-ABP01	900 x 900 x 1200 (W x D x H)

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REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR

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URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the installation of the Autoclave cum Bung Processor
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.

Prepared by**Name/ Designation****Signature****Date**

Ms. Sandhya Samant
Sr. Engineer – Projects (Biotech)
NNE Pharmaplan India Ltd.

Checked by**Name/ Designation****Signature****Date**

Mr. Vikas Katial
GM-Head COC Vaccines
NNE Pharmaplan India Ltd.

Approved by**Name/ Designation****Signature****Date**

Mr. Narendra Prasad
Director-Technical
NNE Pharmaplan India Ltd

HLL Lifecare Limited

PII, Coonoor

Authorized by**Name/ Designation****Signature****Date**

Project Authority
PII, Coonoor

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2.0 EQUIPMENT DESCRIPTION

A double door Autoclave cum Bung Processor is an industrial autoclave especially designed for washing & steam sterilization of rubber closures.

S.No.	Identification no.	Process	Chamber inner Dimension (W x H x D in mm)
1.	F-ABP 01	To sterilize 90,000 rubber bungs/cycle of size 20 mm	900 x 1200 x 900 in mm

Autoclave cum Bung Processor will be used for steam sterilization and drying of rubber closures and filling machine components and other required articles if any.

The equipment will consist of the following components:


- Jacketed Chamber
- Horizontal Sliding door with proper gasket retraction during opening and closing operation
- The dosing system (with low level switch) consisting hopper for storage of the detergent and silicone solution
- Supply nozzles with connection for pure steam and vacuum
- Steam condensate trap assembly
- Vent filter with assembly for SIP
- Control panel with PLC, HMI, temperature trend chart (colored) recording and printing software
- Sensors: RTD and pressure transmitter
- Pressure reducing valve for regulating the pure steam inlet to the chamber
- Pressure reducing valve for regulating the plant steam inlet in the jacket
- Compound Pressure gauge
- Cartridge filter at the user point of clean utilities to be provided.
- Cartridge filters housing in the recirculation loop.
- Integrated vacuum system
- Bio shield to seal the sterile and non-sterile areas.

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 becomes necessary the item must be clearly stated.
4.	In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column.
5.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
6.	The Technical Specification serves to define a summary of all 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 <ol style="list-style-type: none"> If no comments against any specification shall be considered as "NO" and 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 HBL before submitting the quotes.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL 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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3.0 PROCESS DESCRIPTION

3.1 Input & Charging method

3.1.1	Articles/Accessories like filling machine change parts, Aluminum flip off seals, Garments, silicone tubing etc will be loaded manually on the loading carriage.	
3.1.2	Rubber stopper for washing and sterilization shall be loaded manually on the movable loading carriage.	
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 loading carriage should be provided with removable shelves for more flexibility and carriage floor trolley MOC shall be of SS304	
3.1.5	The loading trolley shall be provided for putting the loading carriage or movable loading carriage on loading and unloading sides of autoclave (Total 4 Nos.). Vendor to specify the size of the trolley to accommodate in the existing layout.	
3.1.6	Vendor shall design appropriate movable loading carriage for rubber closures and aluminum seals to be used for washing, siliconization (only for rubber stoppers) and sterilization in the same autoclave.	
3.1.7	Washed and ready to use equipment parts, garments etc. will be packed in tyvek bags before loading in the loading carriage for sterilization.	
3.1.8	Vendor to provide the provision for door opening from loading and unloading side during bung processor cycle.	
3.1.9	Loading environment: loading will be from room of Class C (ISO 7)	

3.2 Brief Process Steps


3.2.1	<p>The equipment must operate and control the following process cycle:</p> <ul style="list-style-type: none"> Rubber closure washing, siliconization (for rubber stoppers) (using purified water , detergent and Water for Injection cycle as optional) 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 → heat up →sterilization hold period→ slow/fast exhaust High-pressure high vacuum sterilization cycle (loading → steam/vacuum) Liquid cycle Cycle for sterilization of vent filter Pulsing → heat up → sterilization hold period → exhaust → vacuum drying → vacuum bleeding by sterile air. 	
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3.3 Output & Discharging method

3.3.1	Washed and sterilized rubber stopper shall be unloaded from the movable carriage automatically to the sterile containers under LAF with background Class B.	
3.3.2	Other sterilized articles will be unloaded from the carriage manually in Aseptic area.	
3.3.3	The unloading trolley shall be provided for easy unloading of the loading carriage.	

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Specifications		Remarks
4.0 PRODUCTIVITY REQUIREMENT		
4.1 Desired/ suggested capacity		
4.1.1	The equipment must be suitable for loading minimum 90,000 rubber closure (Size-20 mm) per cycle. Internal Chamber Size: 900 x 1200 x 900 (mm) (W x H x D in mm) <u>Note: 1 Cycle for 90,000 bungs of size 20 mm</u>	
4.2 Standard batch size		
	90,000 bungs per cycle	
4.3 Change Over Time		
	Not applicable	
4.4 Other Productivity Requirement		
	Not applicable	
5.0 CONTAINMENT		
	Not Applicable	
6.0 GMP REQUIREMENTS		
6.1 Process control		
6.1.1	The autoclave should essentially have the necessary provision for adjustment / control of the following critical process.	
	a) Rubber closure washing, siliconization and sterilization cycles (Using purified water and Water for Injection, detergent cycle as optional)	
	b) Vacuum leak test cycle (As per HTM 2010)	
	c) Bowie Dick cycle (17 min at 121 °C and 3.5 min at 135 °C)	
	d) Standard sterilization cycle (loading → heat up → hold period→ slow/fast exhaust	
	e) High-pressure high vacuum sterilization cycle (loading → steam/vacuum pulsing → heat up → hold period → exhaust → vacuum drying → vacuum bleeding by sterile air from cooling zone.	
6.1.2	For the above processes following are the critical process parameters which must be controlled by the equipment	
	Rubber closure washing and siliconization:	
	Wash-I	
	1. Machine wash	
	2. Detergent In	
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3. Detergent flushing	
4. Fluidization	
5. Stabilization	
6. Purified water overflow	
7. Drain	
8. Machine wash	
9. No. of repeats	
Wash-II	
10. Fluidization	
11. Stabilization	
12. Purified water overflow	
13. Drain	
14. Machine wash	
15. Drain	
16. No. of repeats	
Wash-III	
17. Stabilization	
18. Drain	
19. Machine wash	
20. Drain	
21. No. of repeats	
Siliconization	
22. Silicon In	
23. Silicon flushing	
24. Silicon soaking	
25. Drain	
26. Machine wash	

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Specifications	Remarks
27. Drain	
28. No. of repeats	
Steam sterilization	
29. Pre vacuum	
30. Pre pressure	
31. No. of pre pulses	
32. Heat up	
33. Heat up hold	
34. Heat up control band	
35. Small valve set point	
36. Sterilization hold temperature	
37. Sterilization hold time	
38. Temperature control band	
39. Overshoot temp	
40. Sterilization stop temp	
41. Sterilization reset temp	
42. Post vacuum start pressure	
43. Post vacuum	
44. Post vacuum hold time	
45. Post pressure	
46. No. of post pulses	
47. Exhaust On	
48. Exhaust off	
49. Cooling pressure	
50. Cooling time	
51. Jacket drain time	
52. Process end pressure	

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53. Chamber pressure high	
54. Too long time for pre vacuum	
55. Too long time for heat up	
56. Basket drive on time	
6.1.3 Recipe modification option shall also be provided.	

6.2 Failure mode detection

6.2.1	The autoclave cum bung processor shall be capable to detect the failure, notify the operator with audio/ video alarm and shut down the process	
6.2.1.1	Process critical parameter exceed defined limit	
6.2.1.2	Failure of critical equipment component which can affect the product quality directly or indirectly	
6.2.1.3	Failure in utility supply: <ul style="list-style-type: none"> Compressed air pressure low Plant steam pressure low Pure steam pressure low Softened water pressure low detergent & silicon oil low 	
6.2.1.4	Failure in data communication	
6.2.1.5	GxP critical test failure	
6.2.1.6	Vendor shall propose detail list of alarms and interlocks in functional specification. The alarms and interlocks list shall be finalized with the final user during discussion of detail engineering design of the equipment.	
6.2.1.7	Emergency stop activated	
6.2.1.8	Power failure	
6.2.2	Following condition (not limited to the mentioned below) need only notification	
6.2.2.1	End of cycle	
6.2.2.2	Door opening after end of cycle	
6.2.2.3	Compressed air supply less than required for pneumatic operation	
6.2.2.4	The required vacuum not achieved for a long period of time (The time can be set)	
6.2.2.5	Vacuum leak test failure.	
6.2.2.6	Vacuum pump over load.	
6.2.2.7	Vacuum pump failure.	

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6.3 In –Process control

Manual diaphragm valves to be provided as sampling valves for pure steam & chamber condensate sampling as per the HTM/ EN 285 guidelines.

Manual ball valve for side pocket 7 recirculation sampling valve


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	Sterilization 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	N	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	Y	Y	N

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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 transmitter-2 No	To give pressure input to PLC and HMI	0 to 10.0 bar	0.1 bar	Y	Y	Y	Y		
Temperature transmitter-3 Nos	To convert temperature input to 4-20 mA	0°C to + 150°C	0.1°C	Y	Y	Y	Y		
Temperature Indicator cum controller-1 No	For manual operation in case of PLC failure and indication of chamber temperature	0°C to + 150°C	0.1°C	Y	Y	Y	Y		
<p>@ At least 5 – 6 points in the chamber excluding the condensate drain should be considered.</p> <p>Y Required, N Not required</p>									

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 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.
- The door shall not open with a chamber temperature inside. (More than 50 degree centigrade approx)

6.6.4 Temperature trend chart recording and printing software to be provided.

6.6.5 Vacuum pump to be provided with the system.

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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 detector probe as per HTM 2010	
6.6.8	Jacket to be provided with steam trap.	
6.6.9	Sampling valve in the condensate drain line for collection of condensate sample.	
6.6.10	Steam traps shall be provided with the system wherever it is required.	
6.6.11	Vendor to give code numbers for each component.	
6.6.12	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.	
6.6.13	These unique identifiers will be shown on all Process & Instrumentation (P&I) drawings and General Arrangement drawings.	
6.6.14	Upon equipment delivery, Vendor shall supply Client with a register containing all details of equipment numbers issued.	
6.6.15	All valves and instruments are to be physically labeled with their equipment numbers	
6.6.16	All the sterile side valves to be of Diaphragm type.	
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	Double door with horizontal sliding and chamber shall be horizontal type.	
6.7.3	The chamber trolleys should be provided with removable shelves for more flexibility if required. The chamber trolley shall be 4 in number; e.g. two for autoclave and another two for bungs (sterile and non-sterile). 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	The dozing system (with low level switch) consisting hopper for storage of the detergent and silicone solution.	
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 vendors scope.	
6.7.7	Analogue module with back up	
6.7.8	The exhaust side of the machine should be provided with a vent filter for the sterilization of the exhaust air. Provision for sterilization of the same to be provided.	
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.	

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<p>6.7.11 Sterilization Chamber:</p> <p>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.</p> <p>The sterilizer shall be able to reach and maintain sterilization temperature of 121 ° to 134 °C. The temperature shall be settable parameter.</p>	
<p>6.7.12 Chamber Doors:</p> <p>Steam Sterilizers 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.</p> <p>The door gaskets shall be made of high temperature resistant silicone rubber with rounded corners</p>	
<p>6.7.13 Door Safety</p> <p>The following door safety features shall be provided for operator safety:</p> <p>Door interlocking to prevent simultaneous opening of both the doors.</p> <p>Door Process Lock to prevent opening of doors when the process is on</p> <p>Door obstructive sensor to be provided</p>	
<p>6.7.14 Validation port:</p> <p>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</p>	
<p>6.7.15 Vacuum Break Filter:</p> <p>A 0.2-micron vacuum break filter shall be provided on the sterile side for pressure equalization after vacuum creation</p>	
6.7.16 Maintenance and utility shall be on one side only.	
6.7.17 Connection to drains shall be in vendor scope.	
6.7.18 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.	
6.7.19 Equipment should be flushed with wall on both non-sterile and sterile side with bio seal.	
<p>6.7.20 During FAT/SAT the following need to be demonstrated:</p> <ol style="list-style-type: none"> All probes to reach 121°C±3°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 ±1.6% over the range of 1 bar to 3 bar. Pressure recorders shall have an accuracy of at least 0.01 bar 	
6.7.21 All valves on the sterile side should be of Diaphragm type.	

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7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the area as follows.

Equipment Location:

Floor: Ground floor-Formulation

Room size: 10 m²

Room height: 5.5 m (Technical area) Class 'D'

False ceiling height: 3m

Plant: Revival of DPT Vaccine Manufacturing Facility

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

Physical condition of the rooms:

Washing (F1G032)

1. Room will be non-hazardous
2. Class: EU Class "D"
3. Room Size: 41 m²
4. Differential Pressure: 15 Pa Absolute
5. Temperature maintained: 22°C ±2°C
6. Relative Humidity: < 55 % RH

Loading side: Preparation (F1G032A)

1. Room will be non-hazardous
2. Class: EU Class "C"
3. Room size: 44 m²
4. Differential Pressure: 45 Pa Absolute
5. Temperature maintained: 22°C ±2°C
6. Relative Humidity: < 55 % RH

Receiving Sterile Material: Cooling area (F1G056)


1. Room will be non-hazardous
2. Class: EU Class "B"
3. Room size: 20 m²
4. Differential Pressure: 55 Pa Absolute
5. Temperature maintained: 22°C ±2°C
- Relative Humidity: < 55% RH

7.2 Available Utility

- Electricity: _____ (Report Requirement)
- Compressed air: 8-10 bar g (Report Requirement)
- Softened water: 3-5 bar (Report Requirement)
- Purified water: Amb (Report Requirement)
- Pure Steam: 3 bar (Report Requirement)

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REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR

nne pharmaplan®	User Requirement Specifications				
	Equipment/System	Autoclave cum Bung Processor			
	Identification	F-ABP 01	Document	URS/F-ABP 01	
	Effective Date	2013-10-07	Revision	04	

Specifications	Remarks
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- Plant steam: 3-3.5 bar (Report Requirement)
 - WFI: 80-85 °C (Report Requirement)
- Note: Vacuum system to be supplied by the Vendor**
The vendor should plan accordingly for any change

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8.0 ABBREVIATION

List of abbreviations

HTM	Health Technical Memorandum
ISO	International Standard Organization
LAF	Laminar Air Flow
PLC	Programmable Logic Controller
NNE	Novo Nordisk Engineering
ABP	Autoclave cum Bung Processor
SS	Stainless steel
URS	Users requirement specification
HMI	Human Machine Interface

REVISION INDEX

Revision	Date	Reason for revision
00	2012-09-12	First Draft for Client's Review
01	2013-03-25	Format has been changed by HLL
02	2013-04-16	As per meeting held between HLL and NPI on 9 th & 10 th April
03	2013-06-24	As per the comments from HLL by email dtd:2013-06-17
04	2013-10-07	As per the comments from HLL by email dtd:2013-10-07

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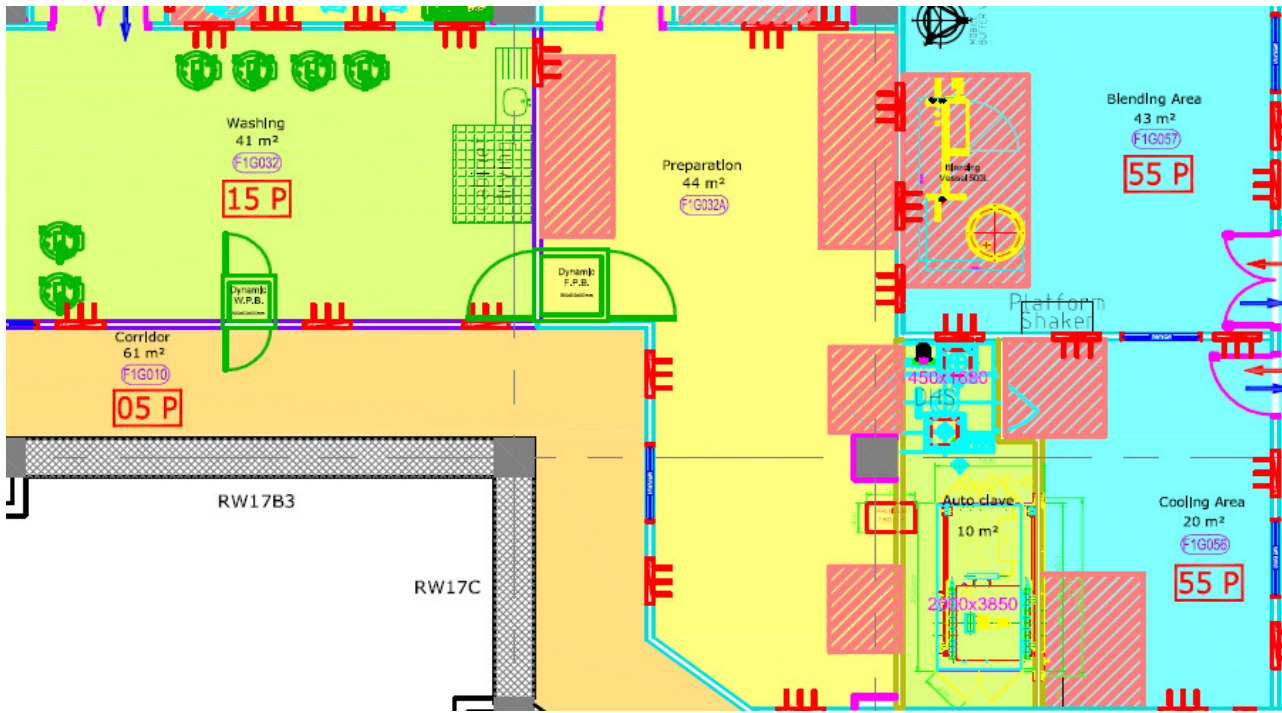
User Requirement Specifications

Equipment/System	Autoclave cum Bung Processor		
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URS Annexure 1: LAYOUT POSITION

Washing (F1G032), Preparation (F1G032A) and Receiving Sterile Material (F1G056)



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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	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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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