DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

AUTOCLAVE CUM BUNG PROCESSOR

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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1.0 PRE – APPROVAL:

PREPARED BY:

Organization	Name	Designation	Signature	Date

CHECKED BY:

Organization	Name	Designation	Signature	Date

APPROVED BY:

Organization	Name	Designation	Signature	Date

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2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Autoclave cum Bung Processor (Make: Auriga International)** for ……...
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.

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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Post Approval of Qualification Protocol after Execution.

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5.0 BRIEF EQUIPMENT DESCRIPTION:

Standard Autoclave Cum Bung Processor is a Jacketed Pressure Vessel. The Standard Steam Sterilization cycle is initiated by introducing Steam into the Jacket. This essentially aids in Preheating the Chamber and Effective Utilization of Heat Energy.

When a Particular Pressure inside the Jacket is achieved, Steam is introduced into the chamber. Air being heavier than Steam is displaced by Gravity Displacement Method which ensures Uniform Steam Distribution and Penetration. The equipment is also provided with Steam Traps with Air Vent to ensure Maximum Air Removal and Steam Condensate without allowing steam to pass through it.

As the Temperature of the Chamber increases, and reaches to the Sterilization Temperature, the control system in place controls this temperature for the Sterilization Time.

After the sterilization hold period is completed, steam from the chamber is exhausted to bring the chamber pressure to atmosphere.

The High pressure High Vacuum Steam Sterilization Process consists of following phases:

- Vacuum steam pulsing
- Heat up
- Sterilization hold
- Vacuum drying
- Sterile air in

The Standard Steam Sterilization Process consists of following phases:

- Heat up
- Sterilization hold
- Exhaust

A double door Steam Sterilizer is an industrial steam sterilizer especially designed for:

- Loading, Washing, Siliconization, Steam Sterilization and Drying of Rubber Bungs.
- Steam Sterilization of Flip-off Seal.
- Steam Sterilization of Garments.
- Steam Sterilization of Filtration Accessories.
- Steam Sterilization of Media.
- Steam Sterilization of Filling Machine Components, Manufacturing Accessories etc.
- Steam Sterilization of Blender.

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6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared ……. The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Autoclave cum Bung Processor is designed for Sterilization of rubber stoppers, articles and supporting accessories which involves in manufacturing activities.	All the rubber stoppers, loaded articles and supporting accessories should be sterile after performed the validated cycles.	Process Requirement
Working: In this process, Steam introduces in the chamber and it acts or works on the placed articles or container which is being kept in the chamber for sterilization.	During Steam Sterilization, Steam distribution should be uniform in the chamber.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

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7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria			
Utility connections should be available as per the manufacturer's specification.				
	Pure Steam for Chamber	**Plant Steam for Jacket**	**Process Air (Fluidization)**	**Process Water (WFI)**
Pressure	1.2 - 1.4 kg/cm^2	1.5 kg/cm^2	3 – 4 kg/cm^2	3 kg/cm^2
Quality	Dry & Saturated	Dry & Saturated	Oil free	WFI
Line Size	¾" NB	¾" NB	¾" OD	1" OD
End Connection	Triclover	Triclover	Triclover	Triclover
	Compressed Air (Lubricated)	**Process Water (Purified) Softened**	**Water for Vacuum System**	
Pressure	6 – 7 kg/cm^2	3 kg/cm^2	1.2 kg/cm^2	
Quality	Dry & Saturated	Purified Water	Softened Water, less than 25 ºC	
Line Size	½" NB	1" OD	¾" NB	
End Connection	Triclover	Triclover	Triclover	
Electricity	**Power:** 415 V – 3 PH – 50 Hz AC, 4 Wire Supply. **Control:** 230 V – 1 PH – 50 Hz Stabilized AC Supply.			
Connected Load	Inductive Connected Load : 6.5 HP			

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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Chamber	Internal Size : 900 (W) X 900 (H) X 1200 (D) mm Plate Thickness : 6 mm Chamber Volume : 972 Liters. Capacity : 50,000 Stoppers of 20 mm Diameter
Jacket	Type : Full Plate Thickness : 5 mm
Air pocket	Plate Thickness : 5 mm
Shell Insulation	Insulation Material : Resin Bonded Glass wool Insulation Thickness : 50 mm Insulation Skin Temperature : (Avg.) 55° C Insulation Cover Insulation Cover Thickness : 24G Insulation Cover Finish : Ra ≤ 1.0
Validation Port with Dummy Adaptor	No of probes in each port : 8 Any Qty : 2 Nos.
Door	Type : Horizontal Sliding Quantity : Two Finish : Ra ≤ 0.8
Door Insulation System	Material Resin Bonded Glass wool Thickness : 50 mm Outer Cover Material Thickness : 1.21 mm (18G)
Door Components	**Door Operating Cylinder** Make : Janatics Type : Double Acting Mounting : Horizontal Size : 63 Bore X 1005 Stroke Qty : 2 Nos. Function : Door Operation.

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Critical Variables	Acceptance Criteria
Solenoid Valves for Door Operating Cylinder	Make : Festo Model : JMFH - 5¼, Double coil Pneumatic Pressure : 0.5 – 8.0 Bar Coil Supply : 1 PH – 230V – 50Hz Qty : 2 Nos. Function : To operate the door cylinders.
Solenoid Valves for Gasket Pressurization/Retraction	Make : Patcon Model : 2 Way On / Off Supply : 1PH – 230V – 50Hz Qty : 5 Nos. Function : To pressurize and retract the gasket to facilitate the door Opening and closing.
Pressure Switch	Make : Indfos Model : RT 110 SB Range : 0.2 – 3.6 bar Qty : 2 Nos. Function : To set the pressure level for the gasket on Unloading and Loading Side
Vacuum Switch	Make : Indfos Model : RT 121 Range : 760 mm to 100 mm of Hg (Vacuum) Qty : 2 Nos. Function : To set the vacuum level for the gasket on the Unloading and Loading Side.

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Critical Variables	Acceptance Criteria
Gauges	**Compound Gauge (Jacket)** Make : Waaree Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm^2 (g) MOC : SS316 for Contact Part Accuracy : ± 1% FS Connection : 3/8" BSP, Back Connection Location : Loading Side Qty : 1 No Function : Indication of Jacket Pressure **Compound Gauge (Chamber)** Make : Waaree Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm^2 (g) MOC : SS316 for Contact Part Accuracy : ± 1% FS Connection : 3/8" BSP, Back Connection Location : Loading Side Qty : 2 No Function : Indication of Chamber Pressure

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Critical Variables	Acceptance Criteria
	Compound Gauge (Gasket) Make : Waaree Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm^2 (g) Accuracy : ± 1% FS Connection : 3/8" BSP, Back Connection Qty : 3 Nos. Locations : Gasket1 : On Loading Side Gasket2 : On Unloading & Loading Side Function : Indication of Gasket Pressure.
Filter Regulator Lubricator	Make : Janatics Size : ¼" BSP Range : 0 To 10 Bar Function : To filter, regulate & lubricate the incoming compressed air
Regulator	Make : Janatics Size : ¼" BSP Range : 0 To 10 Bar Qty : 2 Nos. Function : One is used for door operation & other is used for gasket Pressurization.
Ejector	Make : Festo Model : VAD 3/8 Size : 3/8 BSP Function : To retract door gasket before opening door.

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Critical Variables	Acceptance Criteria
Limit Switch	Make : Bohmen Model : 1 NO + 1 NC Type : Roller Lever Qty : 4 Nos. Function : Sensing the door position
Photocell Sensor	Make : P & F Type : Single Path Model : M5/MV5/32/115 Qty : 2 Sets Function : Door Obstruction Safety.
Piping	Piping Material : SS316L for Contact Part End Connection : Triclover Piping Material : SS316L for Non Contact Part End Connection : Threaded Welding : Argon Welding

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Critical Variables	Acceptance Criteria
Pneumatic Piston Type **Valve with Solenoid**	Make : Madho MOC : SS316L Type : Single Acting End Connection : Triclover **Valve** Jacket Steam in : 1" BSP Chamber Exhaust : ½" OD TC Chamber Process Air in : 1" OD TC Chamber Air Out : 1" OD TC Chamber Condensate : 1" OD TC Chamber Steam in : 1 ½" OD TC Side Pocket Drain : 1" OD TC WFI in : 1½" OD TC Purified Water in : 1½" OD TC Silicon Fluid in : ½" OD TC Chamber Drain : 2" OD TC Detergent in : ½" OD TC
Manual Diaphragm Valve	Make : President MOC : SS316L MOC of Diaphragm : PTFE back with EPDM End Connection : Plain End
	Condensate Sampling : 8 mm OD Chamber Pure Steam Sampling : 8 mm OD
Manual Ball Valve	Make : President Type : 3 PC Design End Connection : Threaded/ Triclover Chamber Exhaust : ½" BSP (SS304) Chamber Steam in : ½" OD TC (SS316L) Recirculation Sampling : ½" OD TC (SS316L) Side Pocket Sampling : ½" OD TC (SS316L) Chamber Drain : 1 ½" OD TC (SS316L)

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Critical Variables	Acceptance Criteria
Manual Needle Valve	Make : President MOC : SS304 End Connection : Threaded Chamber Condensate : 1" BSP
Non Return Valve	Make : President MOC : SS316L End Connection : TC End Chamber Process Air In : 1" OD TC
Non Return Valve	Make : Leader MOC : Brass End Connection : Threaded Chamber Condensate : 1" BSP
Safety Valve	Make : Teleflo MOC : SS304 Type : Spring Loaded Range : 0 to 3 kg/cm^2 (g) End Connection : Threaded To protect the jacket from over pressure conditions : 1" X 1" BSP To protect the chamber from over pressure conditions : 1 ½" X 1 ½" BSP
Steam Trap	Make : Spirax Marshall • Type : Float Type • MOC : Cast Iron with Brass Contact Parts • End Connection : Threaded Jacket Condensate : ¾"

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Critical Variables	Acceptance Criteria
Float Switch	Make : Mahalaxmi Type : Side Mounted MOC : SS316 No of Contacts : 1 NO + 1 NC Qty: 2 Nos. To control the level of water in the Chamber (High) Model : SMT–16– F82 To control the level of water in the Chamber (Low) Model : SMT–16– F82
Regulator	Make : Janatics Range: 0 To 10 Bar End Connection : Threaded To regulate the incoming Process Air : 1” BSP
Pressure Switch	Make : Indfos MOC : SS304 Range : 0.2 – 3.6 bar End Connection : Threaded Qty : 2 Nos. To set pressure level of Jacket Model : RT 110 SB To set pressure level of Chamber Model : RT 110 SB

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Critical Variables	Acceptance Criteria
Pressure Switch	Make : Indfos MOC : SS304 Range : 0.5 – 10.0 bar End Connection : Threaded/ Triclover Qty : 2 Nos. To set pressure level of Compressed Air Model : RT 110 SB To set pressure level of Process Air Model : RT 110 SB
Pressure Switch	Make : Indfos MOC : SS304 Range : 0.5 – 7.0 bar End Connection : Threaded/Triclover Qty : 4 Nos To set pressure level of Softened Water Model : RT 110 SB (SS304) To set pressure level for Pure Steam Model : RT 110 SB To set pressure level of Purified Water Model : RT 110 SB To set pressure level of WFI Model : RT 110 SB
Water Filter	Make : Kumar Process Material : SS316L Retention : 10 Micron Dimension : 10” long with housing size Size : 1” OD TC End Connection: Triclover

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Critical Variables	Acceptance Criteria
Re Circulation Pump	Make : Kiron Pumps HP/RPM : 1 HP/2900 RPM Range : 20 LPM TO 140 LPM Supply : 230 V – 1 PH – 50 Hz
Geared Motor	**Gear box** Make : Bonfiglioli (Heliworm Gear) Model : WR 86V .300.P71B.5.B3 Output RPM : 4.7 RPM **Motor** Make : Hindustan HP/ RPM : 0.5 HP/ 2790 RPM
Spray nozzle at top	Make : Spray tech Type : Self Rotating Ball Type Discharge : 30 LPM Qty : 6 Nos
Vacuum Pump & Motor	Make : New Genre Type : Watering Type Model : LWV - 12 Capacity : 120 m^3/hr Location : On Skid Motor : Crompton HP/RPM : 3.0 HP / 2880 RPM Function : To create vacuum in the chamber.
Steam Condenser	Type : Shell & Tube Transfer Area : 0.36 m^2 Material : SS304 Function : To condense the exhaust steam (from chamber) before entering the vacuum pump

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Critical Variables	Acceptance Criteria
Pneumatic Piston Type Valve	Make : Madho Type : Single Acting End Connection: Triclover/ Threaded Chamber Vacuum : 1 ½" OD TC Chamber Filter Air in : ½" OD TC Vacuum Pump Softened Water in : ¾" BSP
Non Return Valve	Make : President / Leader End Connection : Threaded Chamber vacuum : 1 ½" BSP Vacuum Pump Drain : ½" BSP
Air Filter	Make : Sartorious Size : 1½" OD TC Filter Retention : 0.2 micron Location : On Unloading side Function: To filter the air before entering into the chamber.
Switch Gear	Contactor – Siemens Miniature Circuit Breaker – Siemens Over Load Relay – Siemens Indication Lamp – Mimic Terminal Block – Connectwell

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Critical Variables	Acceptance Criteria
Control Indication On Unloading Side	**Push Buttons with indication lamps** Colour coded push buttons with indication lamps are provided for the following: 1. Unloading door open. 2. Unloading door close. 3. Unloading door open acknowledge. 4. Auto Unloading Rotary Switch. 5. Emergency stop. **Indication lamps** Colour coded indication lamps are provided for the following: 1. Door precondition indication. 2. Process on/end indication. **Push Buttons with indication lamps** Colour coded push buttons with indication lamps are provided for the following: 1. Loading door open. 2. Loading door close. 3. Rotating Basket Inching. 4. Emergency stop. 5. Control on/off switch **Indication lamps** Colour coded indication lamps are provided for the following: 1. Door precondition indication. 2. Alarm Indication.
MMI	The operator interface is fitted onto the Control Panel on the Loading side.
Printer	The Printer is fitted onto the Control Panel on the Loading side.
Strip Chart Recorder	The Strip Chart Recorder is fitted onto the Control Panel on the Loading side.

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Critical Variables	Acceptance Criteria
PLC	Make : Mitsubishi Model : FX1N 24 MR-ESS No of digital inputs: 14 Nos. No of digital inputs used: 14 Nos. Type of input : 24V DC No of digital outputs: 10 Nos. No of digital outputs used : 10 Nos. Type of output : 230V AC Function: To control the process Automatically.
Extension Card (O/P Card)	Make : Mitsubishi Model : FX2N 8EYR-ES No of digital outputs: 8 Nos. No of digital outputs used: 8 Nos. Type of output : 230V AC Function: To add additional output to PLC.
Analog Input Card	Make : Mitsubishi Model: FX2N 4 AD-PT No of analog inputs: 4 Nos. No of analog inputs used: 4 Nos. Type of analog input : Pt 100 Qty : 1 No Function: To give analog input to PLC.
Analog Input Card	Make : Mitsubishi Model : FX1N 2AD-BD No of analog inputs : 2 Nos. No of analog inputs used : 2 Nos. Type of analog input : 4- 20 mA Qty : 1 No Function : To give analog input to PLC

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Critical Variables	Acceptance Criteria
MMI	Make: Mitsubishi Model: Beijers E -1063 Printer Port : Rs 232 Function: To start the process & display online parameters.
D.C. Source	Make : Shavison Model : G31 – 60 – 24 Type : SMPS I/P Voltage : 230V AC O/P Voltage : 24 V DC, 2.5 A Function : To provide 24 V DC, 2.5 A supply to PLC.
Pressure Transmitter	Make : Keller Range : -1 to 3 bar Accuracy : 0.25% O/P : 4 -20 mA End Connection: ½” BSP Qty : 1 No Function : To give pressure input to PLC & SCR.

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Critical Variables	Acceptance Criteria
Temperature Sensor	**Inside the chamber** Make : Radix Type : Pt100/ Duplex/ 3 Wire/ Flexible Size : 6 mm Tip Dia X 2“ Long Cable Length : 5 Meter Long Accuracy : Class A Range : 0 To 150 ºC Qty : 4 Nos. **Chamber Condensate** Make : Radix Type : Pt100/ Duplex/ 3 Wire/ Fixed Size : 6 mm Tip Dia X 4“ Long Accuracy : Class A Range : 0 To 250 ºC Qty : 2 Nos.
Strip Chart Recorder	Make : G-TEK No of Channels : Six No & Type of Inputs : 5T + 1P Temperature: 5 Nos., Pt100, 3 Wire Range : 0 to 2000C Pressure : 1 No, 4-20 Ma Range: -1 to 3 bar
Temperature Indicator Cum Controller	Make : Radix Type : Double Set Point Range : 0 To 200 ºC Qty : 1 No Function : For manual operation in case of PLC failure.

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Critical Variables	Acceptance Criteria
Carriage	Type : Full Material : SS316L Qty : 1 No Arrangement : Shelves Type : Perforated Spacing : Equi-spaced
Trolley	Type : Full Material : SS304 Qty : 3 Nos.
Rotating Carriage	Type : Full Material : SS316L Qty : 1 No
Auto Unloading Chute Trolley with chute	Material : SS304 Qty : 1 No

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts name	Material of construction
1.	Chamber	SS316L
2.	Jacket	SS304
3.	Air pocket	SS304
4.	Insulation cover material	SS304
5.	Stand	SS304
6.	Skid	SS304
7.	Rail pipe	SS316L
8.	Steam & vacuum baffle	SS316L
9.	Validation port with dummy Adaptor	SS316
10.	Door	SS316L
11.	Door insulation system	SS304
12.	Door components	SS304
13.	Pneumatic piston type Valve with solenoid	SS316L
14.	Manual Diaphragm Valve	SS316L
15.	Chamber Exhaust	SS304
16.	Chamber Steam in	SS316L
17.	Recirculation Sampling	SS316L
18.	Side Pocket Sampling	SS316L
19.	Chamber Drain	SS316L
20.	Manual Needle Valve	SS304

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S.No.	Parts name	Material of construction
21.	Non Return Valve (TC End)	SS316L
22.	Non Return Valve (Threaded)	Brass
23.	Safety Valve	SS304
24.	Steam Trap	Cast Iron with Brass Contact Parts
25.	Float Switch	SS316
26.	Pressure Switch	SS304
27.	Water Filter	SS316L
28.	Gear box	SS316L
29.	Steam Condenser	SS304
30.	Pneumatic Piston Type Valve	SS316L

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7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Earthing	Proper Earthing should be provided.	Safety Requirement
Door Safety	Both doors will not open simultaneously. No door opening when the process is on. Process will not start either in auto or manual if either side door is open.	Safety Requirement
Door Obstruction Safety	The door will retract to open if obstructed by hand or by any other object	Safety Requirement
Door/Gasket Operation	Electro – Pneumatic	Safety Requirement
Door Locking System	Pneumatic through process	Safety Requirement
Alarms	• High temperature and pressure. • Sterilization timer stop in case of temperature drop. • Sterilization timer reset in case of temperature drop. • Too long time to create vacuum. • Too long time to heat up. • Vacuum Pump Trip • Utility failure alarm	Safety Requirement

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7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the autoclave cum bung processor	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in PO and URS.

(2) Operating and service manual for Autoclave Cum Bung Processor.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
DQ	:	Design Qualification
Hr	:	Hour
mm	:	Millimeter
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature Circuit Breaker
db	:	Decibel
CI	:	Cast Iron
RH	:	Relative Humidity
MMI	:	Man Machine Interface
HP	:	Horse Power
SS	:	Stainless Steel
OD	:	Outer Diameter
ID	:	Inner Diameter
HDPE	:	High Density Poly Ethylene

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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			