INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

EQUIPMENT ID. No.	
LOCATION	**Unit Preparation Room**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CONTENTS

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Autoclave cum Bung Processor for ……...
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Autoclave cum Bung Processor (Make: Auriga International)** to be installed in the **Unit Preparation Room.**
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Autoclave cum Bung Processor.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

5.0 EQUIPMENT DETAILS:

Equipment Name	Autoclave cum Bung Processor
Equipment ID.	…….
Manufacturer's Name	Auriga International
Model	…….
Supplier's Name	Auriga International
Location of Installation	Unit Preparation Room

6.0 SYSTEM 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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Unit preparation Room 'I' Block.		
Room Condition	General Room Conditions.		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.2 Installation Checks:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
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 Dia.		
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.) 55ºC 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.		
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.		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
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.		
Gauges	**Compound Gauge (Jacket)** Make : Waaree Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm2 (g) Accuracy : ±1% FS Connection : 3/8" BSP, Back Connection Location : Loading Side Qty : 1 No **Compound Gauge (Chamber)** Make : Waaree Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm2 (g) Accuracy : ± 1% FS Connection : 3/8" BSP, Back Connection Location : Loading Side Qty : 2 Nos.		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Compound Gauge (Gasket) Make : Warree Type : Bourdon Mounting : Panel Range : -1 To 6 kg/cm2 (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.		
Limit Switch	Make : Bohmen Model : 1 NO + 1 NC Type : Roller Lever Qty : 4 Nos. Function : Sensing the door position		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Photocell Sensor	Make : P & F Type : Single Path Model : M5/MV5/32/115 Qty : 2 Sets Function : Door Obstruction Safety.		
Piping	End Connection : Triclover End Connection : Threaded Welding : Argon Welding		
Pneumatic Piston Type Valve with Solenoid	Make : Madho 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 DiaphragmValve	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 Chamber Steam in : ½" OD TC Recirculation Sampling :½" OD TC Side Pocket Sampling : ½" OD TC Chamber Drain : 1 ½" OD TC		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Manual Needle Valve	Make : President End Connection : Threaded Chamber Condensate : 1" BSP		
Non Return Valve	Make : President 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 Type : Spring Loaded Range : 0 to 3 kg/cm2 (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"		
Float Switch	Make : Mahalaxmi Type : Side Mounted 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		

PHARMA DEVILS

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Pressure Switch	Make : Indfos 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		
Pressure Switch	Make : Indfos 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		
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		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
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 Function : To condense the exhaust steam (from chamber) before entering the vacuum pump		
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		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
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		
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		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
MMI	Make : Mitsubishi Model : Beijers E -1068 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.		
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 1500C 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 2500C 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		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Temperature Indicator Cum Controller	Make : Radix Type : Double Set Point Range : 0 To 2000C Qty : 1 No Function: For manual operation in case of PLC failure.		
Carriage	Type : Full Qty : 1 No Arrangement : Shelves Type : Perforated Spacing : Equi-spaced		
Trolley	Type : Full Qty : 3 Nos.		
Rotating Carriage	Type : Full Qty : 1 No		
Auto Unloading Chute Trolley with chute	Qty : 1 No		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.3 MOC Verification List:

Parts name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Chamber	SS316L		
Jacket	SS304		
Air pocket	SS304		
Insulation cover material	SS304		
Stand	SS304		
Skid	SS304		
Rail pipe	SS316L		
Steam & vacuum baffle	SS316L		
Validation port with dummy Adaptor	SS316		
Door	SS316L		
Door insulation system	SS304		
Door components	SS304		
Pneumatic piston type Valve with solenoid	SS316L		
Manual Diaphragm Valve	SS316L		
Chamber Exhaust	SS304		
Chamber Steam in	SS316L		
Recirculation Sampling	SS316L		
Side Pocket Sampling	SS316L		
Chamber Drain	SS316L		
Manual Needle Valve	SS304		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Parts name	Material of construction	Observation	Observed By (Engineering) Sign/Date
Non Return Valve (TC End)	SS316L		
Non Return Valve (Threaded)	Brass		
Safety Valve	SS304		
Steam Trap	Cast Iron with Brass Contact Parts		
Float Switch	SS316		
Pressure Switch	SS304		
Water Filter	SS316L		
Gear box	SS316L		
Steam Condenser	SS304		
Pneumatic Piston Type Valve	SS316L		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.4 Utility Verification List:

Critical Variables	Acceptance criteria				Observed By (Engineering) Sign/Date
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	
Observation					
Quality	Dry & Saturated	Dry & Saturated	Oil free	WFI	
Observation					
Line Size	¾" NB	¾" NB	¾" OD	1" OD	
Observation					
End Connection	Triclover	Triclover	Triclover	Triclover	
Observation					
	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		
Observation					
Quality	Dry & Saturated	Purified Water	Softened Water, less than 25° C		
Observation					
Line Size	½" NB	1" OD	¾" NB		
Observation					
End Connection	Triclover	Triclover	Triclover		
Observation					
Electricity	**Power:** 415 V - 3 PH - 50 Hz AC, 4 Wire Supply. **Control:** 230 V - 1 PH - 50 Hz Stabilized AC Supply.				

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

Critical Variables	Acceptance criteria	Observed By (Engineering) Sign/Date
Observation		
Connected Load	Inductive Connected Load : 6.5 HP	

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.5 Safety:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be Properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Earthing	Proper Earthing should be provided.		
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.		
Door Obstruction Safety	The door will retract to open if obstructed by hand or by any other object		
Door/Gasket Operation	Electro – Pneumatic		
Door Locking System	Pneumatic through process		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

9.0 REFERENCES:

The Principle References is the following

- Validation Master Plan
- Schedule- M-"Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2-Good Manufacturing Practices and Inspection**.**

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

16.0 ABBREVIATIONS:

AC	:	Alternating Current
AMPS	:	Amperes
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
KVA	:	Kilo Volt Ampere
MCB	:	Miniature Circuit Breaker
MOC	:	Material of Construction
PO	:	Purchase Order
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
URS	:	User Requirement Specification
DDA	:	Autoclave cum Bung Processor
P & ID	:	Piping & Instrumentation Diagram
NMT	:	Not More Than
NLT	:	Not Less Than
SS	:	Stain less Steel
NB	:	Nominal Bore
OD	:	Outer Diameter
ID	:	Inner Diameter

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			