



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG
PROCESSOR**

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOCLAVE CUM BUNG PROCESSOR**

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



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG
PROCESSOR**

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**OPERATIONAL 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)			



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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Autoclave Cum Bung Processor and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to qualification of **Autoclave Cum Bung Processor (Make: Auriga International)** installed in the **Unit Preparation Room**.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Autoclave Cum Bung Processor.
- Successful completion of this Protocol Cum Report will verify that Autoclave Cum Bung Processor meet all acceptance criteria and ready for Performance 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	<ul style="list-style-type: none">• Preparation, Review, Approval and compilation of the operational Qualification Protocol Cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.
Production	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report.• Post Approval of Operational Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Autoclave Cum Bung Processor
Equipment
Manufacturer's Name	Auriga International Private Limited
Supplier's Name	Auriga International Private Limited
Location of Installation	Unit Preparation Room

6.0 EQUIPEMENT 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.



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- 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:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Autoclave cum Bung Processor.
- Draft SOP for Preventive Maintenance of Autoclave cum Bung Processor
- Electrical Circuits Diagram.
- Technical specification of equipment.

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 OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

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



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol cum Report				
2.	IQ Protocol cum Report				
3.	Draft SOP for Operation & Cleaning of Autoclave Cum Bung Processor.				
4.	Draft SOP for Preventive Maintenance of Autoclave Cum Bung Processor				

Checked By (Production)
Sign/Date:

Verified By (Quality Assurance)
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8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

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Verified By
(Quality Assurance)
Sign/Date:

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Sign/Date:



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8.3 Verification of Safety & Interlocks:

Safety	Method	Required	Observation	Observed By (Engineering) Sign/Date
Opening of door	When process is running in auto or manual mode operation press unloading or loading door open push button one by one	Door should not open		
Unloading door opening	Unloading door will open only after successful completion of process.	Unloading door should not open		
Door is opened	Keep unloading door open & start the process. Do not pressurize unloading door gasket & start the process. Close the both side door & do not pressurize any one of them door.	Process should not start		
Door obstruction	When door is moving obstruct the door with hand or material.	Door should move back.		

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8.4 Alarm Checks

Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Leak test fail	<ul style="list-style-type: none"> • During vacuum hold period, open filter air in valve by operating manual over ride facility on SLV for some time & then shut off. • The vacuum will be broken. 	At the end of process alarm will generate		
Over shooting of Temperature (Overshoot temp.)	<ul style="list-style-type: none"> • Set over shoot temperature set point 2⁰c more than sterilization temperature & run the process. Let temp. Rise above over shoot temp. Set point. 	Alarm will generate & exhaust valve will open.		
Sterilization hold period counting stop (Ster. Stop temp.)	<ul style="list-style-type: none"> • During ster. hold period after five minutes, stop chamber incoming steam supply. So that chamber temperature will fall down to ster. stop temperature set point • Now, open 	Alarm will generate & counting will Stop when the chambers temp. Attain sterilization temp. The counting will start further from where it was stopped (i.e. After five minute) &		



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Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
	chamber steam supply	alarm will stop		
Sterilization hold period counting reset (Ster. Reset temp.)	During the sterilization hold period, stop chamber incoming steam supply so that chamber temperature will fall down below set point	Alarm will generate & counting will reset to zero		
	Now, open chamber steam supply	When the chamber attains sterilization hold temperature the time counting will start freshly (from zero) & alarm will stop.		
Pure steam pressure low	If the pressure of incoming plant steam drop below the set pressure	Drop in steam pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Softener water pressure low	During the process, put off cooling water utility supply.	Drop in water pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on		



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Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
		MMI.		
Process air pressure low	During the process, shut off process air utility supply or remove the input, physically from the PLC	Drop in air pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Compressed air pressure low.	During the process, increase setting if pressure switch mounted on compressed air inlet utility.	Alarm will be generated & message will be displayed on MMI		
W.F.I. pressure low	During the process, shut off W.F.I. utility supply or remove the input, physically from the PLC	Drop in water pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Purified water pressure low	During the process, shut off purified water utility supply or remove the input, physically from the PLC	Drop in water pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		



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Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Chamber pressure high	Allow the chamber pressure to rise more than chamber pressure high set point by opening the steam in valve manually	Alarm will be generated & exhaust valve will open & message will be displayed on MMI		
Too long time for pre vacuum	Set, TLT for pre vacuum set point less than actual required time (1 or 2 min.)	Alarm will be generated & message will displayed on MMI		
Too long time for post vacuum	Set, TLT for post vacuum set point less than actual required time (1 or 2 min.)	Alarm will be generated & message will displayed on MMI		
Hold for sampling	After wash –2 alarms will be on to take a sample and decide to continue process or repeat.	Alarm indication will be on and process will halt till further inter partition through MMI after taking sample to continue process or repeat wash.		
Vacuum pump trip./basket drive trip	Trip the pump manually by the override provided on overload relay	Alarm will generate & message will be displayed on MMI.		



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Alarm	Method	Required	Observation	Observed By (Engineering) Sign/Date
Too long time for heat up	Set, TLT for heat up set parameter lesser than actual required time (1 or 2 min.)	Alarm will be generated & message will be displayed on MMI		
Plant steam pressure low	If the pressure of incoming plant steam drop below the set pressure	Drop in steam pressure will be sensed by pressure sw. Alarm will generate & message will be displayed on MMI.		
Door precondition fail	During the process, put off compressed air utility supply.	Alarm will generate & message will be displayed on MMI		

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8.5 Safety Valve:

Safety	Method	Required	Observation	Observed By (Engineering) Sign/Date
Working of safety valves	Increase chamber pressure by 15% of the working pressure.	Chamber steam will blow off through safety valve		
	Increase jacket pressure by 15% of the working pressure.	Jacket steam will blow off through safety valve		

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8.6 Parameter Settings For Chamber Vacuum Leak Test:

Parameter	Purpose	Set value	Observations	Observed By (Engineering) Sign/Date
Pre Vacuum	To create maximum vacuum	-0.600 Bar		
Delay before hold	To stabilize vacuum level after shutting off valve & pump	5 Minute		
Vacuum hold time	To check the leakage during hold period	10 Minute		
Acceptable Leakage	Maximum acceptable limit	0.013 Bar		
Process End Pressure	To end the process & open the door.	- 0.030 Bar		

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8.7 Parameter Settings for Bowie Dick test:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	- 0.500 Bar		
Pre pressure	To break the vacuum with steam	0.500 Bar		
No. of pre pulses	To repeat the vacuum pressure pulses	03 Nos.		
Heat up 1	To heat the load gradually.	110°C		
Heat up hold 1	To maintain the temp. Uniformity in the chamber	5 Minute		
Heat up 2	To heat the load quickly.	115°C		
Heat up hold 2	To maintain the temp. Uniformity in the chamber	3 Minute		
Heat up 3	To heat the load quickly & uniformly with faster rate of heating.	119°C		
Heat up hold 3	To maintain the temp. Uniformity in the chamber	2 Minute		
Heat up control band	To control max & min level of chamber temperature during heat up period	0.2 °C		
Small valve sp	To heat the load slowly	120.0 °C		
Ster. Hold temp.	Sterilization	121.4 °C		
Ster. Hold time	To hold the sterilization period as per the set time	17 Minute		
Control band	To control max & min level of	0.3 °C		



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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
	temperature during sterilization period			
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0 °C		
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.9 °C		
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5 °C		
Exhaust ON	To remove air pockets from chamber	5 Sec.		
Exhaust OFF	To remove air pockets from chamber	60 Sec.		

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG PROCESSOR

8.8 Parameter Settings For Standard Process:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	0.00 bar		
Pre pressure	To break the vacuum with steam	0.00 bar		
No. of pre pulses	To repeat the vacuum pressure pulses	0 Nos.		
Heat up 1	To heat the load gradually.	110.0 °C		
Heat up hold 1	To maintain the temp. Uniformity in the chamber	5 Minute		
Heat up 2	To heat the load quickly.	115.0 °C		
Heat up hold 2	To maintain the temp. Uniformity in the chamber	3 Minute		
Heat up 3	To heat the load quickly & uniformly with faster rate of heating.	118.0 °C		
Heat up hold 3	To maintain the temp. Uniformity in the chamber	2 Minute		
Heat up control band	To control max & min level of chamber temperature during heat up period	0.3 °C		
Small valve sp	To heat the load slowly	120 °C		
Ster. Hold temp.	Sterilization	121.4 °C		
Ster. Hold time	To hold the sterilization period as per the set time	30 Minute		
Control band	To control max & min level of temperature during sterilization	0.3 °C		



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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
	period			
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0 °C		
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.0 °C		
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	119.0 °C		
Exhaust on time	To remove air pockets from chamber	10 Sec.		
Exhaust off time	To remove air pockets from chamber	20 Sec.		

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8.9 Parameter settings for HPHV Process:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Pre vacuum	To create vacuum for air removal	- 0.500 Bar		
Pre pressure	To break the vacuum with steam	0.500 Bar		
No. of Pre pulses	To repeat the vacuum pressure pulses	3 Nos.		
Heat up 1	To heat the load gradually.	110 °C		
Heat up hold 1	To maintain the temp. Uniformity in the chamber	5 Minute		
Heat up 2	To heat the load quickly.	115.0 °C		
Heat up hold 2	To maintain the temp. Uniformity in the chamber	3 Minute		
Heat up 3	To heat the load quickly & uniformly with faster rate of heating.	119.0 °C		
Heat up hold 3	To maintain the temp. Uniformity in the chamber	2 Minute		
Heat up band	To control max & min level of chamber temperature during heat up period	0.2 °C		
Small valve set point	To heat the load slowly	120.0 °C		
Ster. Hold temp.	Sterilization	121.4 °C		
Ster. Hold time	To hold the sterilization period as per the set time	30 Minute		
Temp. Control band	To control max & min level of temperature during sterilization period	0.3 °C		
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0 °C		
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this	120.0 °C		



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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
	value during sterilization period.			
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period.	119.5 °C		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar		
Post vacuum	To achieve set level of vacuum	-0.600 Bar		
Post vacuum hold time	To dry the load.	10 Minute		
No. of post pulses	To achieve effective drying	3 Nos.		
Exhaust ON	To remove air pockets from chamber	5 Sec.		
Exhaust OFF	To remove air pockets from chamber	50 Sec.		
Process end pressure	To end the process & allow to unload the material	-0.500 Bar		

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8.10 Bung Processing Process:

Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
1st Wash With Detergent & Purified Water				
Machine wash	To clean the chamber wall with purified water	3 Minute		
Detergent in	To clean the bungs with detergent.	1 Minute		
Fluidization	To create foam to carry out particles from the bungs.	10 Minute		
Delay for stabilization	To stabilize bungs along with foam.	5 Minute		
Purified water overflow	To maintain the water level inside the chamber for overflowing of the foam along with the particles.	10 Minute		
Drain	To drain the water	5 Minute		
Machine wash	To remove the detergent along with particles from the chamber wall.	3 Minute		
Drain	To drain the water	5 Minute		
No. of repeat	To repeat the process for proper cleaning if required.	1 No.		
Bung Processing – 2nd wash with purified water only				
Fluidization	To create the foam for removal of particles from the bungs.	10 Minute		
Delay for stabilization	To stabilize foam along with bungs.	5 Minute		
Purified water overflow	To maintain the water level inside the chamber for overflowing of the foam with	10 Minute		



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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
	particles.			
Drain	To drain the water	5 Minute		
Machine wash	To remove the particles from the chamber wall.	3 Minute		
Drain	To drain the water	5 Minute		
No. of repeat	To repeat the process for proper cleaning if required.	1 No.		
Bung Processing – 3rd wash with WFI water only				
Delay before drain	To hold the water in stabilized condition	5 Minute		
Drain	To drain the water	5 Minute		
Machine wash	To remove particles from the chamber wall.	3 Minute		
Drain	To drain the water	5 Minute		
No. of repeats	To repeat the process for proper cleaning if required.	1 No.		
Bung Processing – Siliconization				
Silicon in	To apply a coat of silicon fluid on the bungs.	1 Minute		
Silicon soaking	For proper Siliconization on the bungs.	10 Minute		
Drain	To drain the water	5 Minute		
Machine wash	To remove the silicon particles from the chamber wall	3 Minute		
Drain	To drain the water	5 Minute		
No. of repeats	To repeat the process for Siliconization.	1 No.		
Parameter settings for Bung Processing (Sterilization)				



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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
Small valve set point	To heat the load slowly.	120.0 °C		
Ster. Hold temp.	Sterilization.	121.4 °C		
Sterilization Hold time	To hold the sterilization period as per the set time.	30 Minute		
Temperature Control band	To control maximum & minimum level of temperature during sterilization period.	0.3 °C		
Overshoot temperature	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0 °C		
Sterilization Stop temperature	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period.	120.0 °C		
Sterilization Reset temperature	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period.	119.0 °C		
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump.	0.200 Bar		
Post vacuum	To achieve set level of vacuum.	-0.600 Bar		
Post pressure	To break the vacuum by filtered air.	-0.100 Bar		
Post vacuum hold time	To dry the load.	10 Minute		



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Parameter	Purpose	Set Value	Observations	Observed By (Engineering) Sign/Date
No. of post pulses	To achieve effective drying	3 Nos.		
Exhaust ON	To remove air pockets from chamber	0 Sec.		
Exhaust OFF	To remove air pockets from chamber	1 Sec.		
Process End Pressure	To end the process & allow to unload the material	-0.500 Bar		
Chamber Water Temperature	--	30.0 °C		
Basket Drive ON	--	120 Sec.		
Basket Drive OFF	--	60 Sec.		

**Checked By
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Verified By

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Sign/Date:

Reviewed By

(Manager QA)

Sign/Date:



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8.11 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

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8.12 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the OFF button Pressed in, Try to cause movement of an Operating function.	The Equipment will be inoperative.		

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9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Health Technical Memorandum 2010 Sterilization Part 3: Validation and verification

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of Draft SOPs.
- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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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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**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOCLAVE CUM BUNG
PROCESSOR**

16.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo Gram
Ltrs	:	Liters



**OPERATIONAL 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)			