INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
VERTICAL AUTOCLAVE

EQUIPMENT ID. No.	
LOCATION	**Washing & Sterilization Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL AUTOCLAVE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL AUTOCLAVE	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Vertical.
- 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 **Vertical Autoclave** to be installed in Washing & Sterilization Area.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vertical Autoclave.

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

5.0 EQUIPMENT DETAILS:

Equipment Name	Vertical Autoclave
Equipment	
Manufacturer's Name	
Model	
Sr.No.	
Capacity	175 Ltr.
Supplier's Name	
Location of Installation	Washing & Sterilization Area

6.0 SYSTEM DESCRIPTION:

The instrument is a fully automatic autoclave controller. It is designed around a powerful micro-controller. As such, it is compact, very rugged and user-friendly. The field wiring is brought on to plug-in type of connectors, thereby reducing down time. The Man-Machine-Interface (MMI) consists of a 16 characters by 2line LCD display with back lit, 6 – keys membrane keypad.

The instrument accepts 1no. RTD sensor as reference for control, and 1 no. RTD sensors for indication only. Sensor break indication is provided and is displayed as "OPEN" against the process value.

The control action is a proportioning on-off type of control with a SSR (solid state relay) drive output.

The heater status is shown on the LED marked 'Heater'.

A pair of potential free contacts is provided and can be used to operate a solenoid valve for Air purge / Steam exhaust. The relay status is shown on the LED marked 'Purge'.

It has provision for sensing low water level with the provision of a level switch. At any time, the level switch activates, an audio alarm is sounded and the display shows "WATER LOW".

The data is date, time & the 4 channels temperature is logged every minute. When requested to print, at the end of the cycle, the data is dumped to the serial printer.

The Autoclave steam sterilizer produces a working pressure of 15 PSI (1.1 kg/cm^2) maximum attainable pressure is 25 PSI (1.7.kg/cm^2). Once autoclaving pressure is reached the control mechanism ensures precise control of conditions within chamber. A timer if installed helps provide selectable cycle soaking time. Precise temperature and time control ensures complete sterile media/glass ware/instruments. The lid and flange are of pressed stainless steel which enhances the construction of the autoclave. The chamber and cover are also made of stainless steel. As an additional safety measure a spring loaded safety valve blows of

steam incase of accidental pressure build up of more then the required pressure, ensuring total safety of operation.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Instrumentation diagram
- Technical specification of equipment
- 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.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Washing & Sterilization area		
Room Condition	General working condition		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		
Check that all components are installed in the location specified in Equipment Location Diagram**.**	All components are installed in the location specified in Equipment Location Diagram**.**		
Check any physical damage to the equipment.	No any physical damage to the equipment.		
Check the proper electrical installation of Vertical Autoclave.	The proper electrical installation of. Vertical Autoclave.		
Are chemicals, acids or reagents stored close to equipment	Strictly avoid		
Check for adequate earthing	Check if earthing is present at incoming supply point		
Tightening of bolts and ring nuts	Check if the rotation is smooth and unobstructed and that lid		

	fits firm after tightening Caution : Avoid using rod or excessive force while tightening this could damage bolts threads		
Lid gasket fitting	Check silicon gasket if it is fitted firm in groove		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.2 Verification of Technical Specification:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Manufacturer	Osword		
Model	QAT-G-175		
Capacity	175 Ltr.		
Sr.No.	……..		
Inner Chamber Dimension	22 x 30 Inch		
Operating Voltage	: 230 ± 10 % V AC		
Analog Input	2 Nos.PT.100 – 3 wire		
Range	0-150 ° C		
Indicating Accuracy	+ /- 0.1 ° C		
Control Accuracy	: +0. 5°C		
Control Output	SSR drive output		
Purging output	1 C/O Relay content (230 / 3 A)		
Alarm output	Peizo- Electric Buzzer Compatible O/P		
MMI	16 x 2 LCD Panel, 6 Key Membrane Keypad.		
Printer Port	RS232 Serial Interface with Programmable baud (1200		
Heater Coupling	1 ¼ ” BSP Qty : 2 Nos		
Wheel	Caster Wheel Qty : 4 Nos		
Coupling on the Lid	¼ ” BSP Qty : 4 Nos		

 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL AUTOCLAVE	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Solenoid valve Coupling	Make : Avcon ½ ” BSP Qty : 1 Nos Function : Release air / Steam shut at 95 to 100 ℃		
Temperature Sensor Coupling	3/8 ” BSP Qty : 1 Nos Type : PT-100 Sr.No. 2851 /1215		
Drain Coupling	3/8 ” BSP Qty : 1 Nos		
Ring/ Stud	3/8 ” BSP MOC : SS Brakelite		
Slotting on lid & Flange	6/8/12 No.		
Chamber Joint grinding Finish	Mirror Finish		
SS Bracket Size	STD		
SS Bracket Stand	STD		
Door Silicon Gasket Fitting	Joint less		
Pressure Gauge	¼ ’’ BSP 30 PSI		
Steam Release Valve	¼ ’’ BSP SS Type : open / shut		
Safety Valve ¼ ’’	¼ ’’ BSP Spring Loaded open at 18 PSI Function : High Pressure Control Sr.No. 1603163		
Timer Function	Set at 20 minute check cut-off		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL AUTOCLAVE	PROTOCOL No.:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Safety Temperature Sensor 3/8 '' BSP SS	Type : PT -100 Sr.No. 2960/021C		
Heater Breakdown Test	1.2 kw /10 sec		
Circuit Breaker	Type : 16/25 amp TC Make : Hogger		
Control Panel Wiring	Crimped / Tied		
Power Consumption	Running Power		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 MOC Verification:

COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Body	SS 304		
Inner Body	SS 316		
Gauge	BSP		
Ring	SS Bakelite		
Basket Stand	SS		

Checked By
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Sign/Date: ……

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

Inference:

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

8.4 Safety Feature:

PARAMETERS	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Electric Safety	MCB Circuit Breaker for overload and short Circuit Protection		
High Pressure Safety	Spring Loaded safety valve set above working pressure release		
High Temperature	Provide in fully automatic model only. Safety Temperature controller cuts off heater in case Temperature exceeds set valve with audio buzzer Indication.		
Low Water level cut off	Provide in fully automatic model only-cuts off power to heater incase Water level in Chamber drops.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

9.0 REFERENCES:

- Design Qualification Party Document
- Installation Qualification Party Document
- Certificate of MOC

10.0 DOCUMENTS TO BE ATTACHED:

- Certificate of MOC
- If any other Document Required.

11.0 DEVIATION FROM PRE-DEFINED 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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16.0 ABBREVIATIONS:

AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practices
MOC	:	Material of Construction
NOS	:	No of Strength
Nos.	:	Number
Pvt.	:	Private
Qty	:	Quantity
SS	:	Stainless Steel
V	:	voltage
VLA	:	Vertical Autoclave

17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

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