OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
VERTICAL AUTOCLAVE

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

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL 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 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 Vertical Autoclave 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 **Vertical Autoclave (Make – ……..)** installed in Washing & Sterilization Area.
- This Protocol will define the methods and documentation used to perform OQ activity the Vertical Autoclave for OQ. Successful completion of this Protocol will verify that Dynamic Pass Box meet all acceptance criteria and ready for Performance Qualification.

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

- DQ Protocol Cum Report
- IQ Protocol cum Report
- Draft for Operation & Cleaning of Vertical Autoclave
- Draft SOP for Preventive Maintenance of Vertical Autoclave

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.

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
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	Draft SOP for Operation & Cleaning of Vertical Autoclave.			
4.	Draft SOP for Preventive Maintenance of Vertical Autoclave.			

8.2 Test Equipment Calibration:

EQUIPMENT/ INSTRUMENTS NAME	EQUIPMENT/ INSTRUMENT ID	CALIBRATION ON	DUE ON	OBSERVED BY SIGN / DATE

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 Operational and Functional Checks:

Operate the Dynamic Pass Box as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY (ENGINEERING) SIGN/DATE
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		
Mains switch	Check if mains ON/OFF switch functions		
Temperature controller	Setting of controller is explained in subsequent pages		
	Check if controller responds to setting commands		
	Confirm if controller is set to required sterilization temperature i.e 121.5ºC		
Safety control (supplied if ordered separately)	Press up/down key and check if control settings vary. Set controller 4 deg above set temperature		

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CRITICAL VARIABLE	ACCEPTANCE CRITERIA	OBSERVATION	CHECKED BY (ENGINEERING) SIGN/DATE
Low water level (applicable for fully automatic model only)	Open the lid and move the low water level sensor float up and down. Observe if power to heaters is cut-off and restored by this movement		
Solenoid valve operation (applicable for fully automatic model only)	Check if valve is open initially during air purge cycle		
	Check if valve opens in the end on completion of cycle to release steam		
Timer operation	Check if timer setting can be varied /changed to different time requirement		
	Check if timer is initialized once sterilization temperature is reached		
	Check if timer cuts-off once set time has elapsed		
Check control action accuracy	Temperature set 121.5ºC Temperature resolution 0.1ºC Temperature accuracy +/- 1ºC		
Observe working of equipment for few cycles	Record no of cycles observed Three cycles		
Check functioning of pressure gauge	At set temperature of 121.5ºC the gauge should indicate a pressure of 15 to 17 PSI		

Check functioning of safety valve	Increase temperature setting of controller to 125ºC observe the safety valve it should release the excess steam generated beyond 17 PSI and should open fully at 18 to 20 PSI thus restricting pressure build up beyond 20 PSI		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.4 Trouble shooting – fault finding:

SYMPTOM	POSSIBLE FAULT	REMEDY	SATISFIED YES /NO	CHECKED BY (ENGINEERING) SIGN/DATE
Equipment not switching On	Power supply stage fault	Check Mains Socket on wall and verify if power 230Volts is present Check mains 3 pin plug for loose contact or burnt wire Check if mains ON/OFF Switch are functioning		
Temperature does not rise / increase No heating	Temperature controller defective. Contactor faulty Heater faulty MCB faulty	Check output terminals of digital controller It should give 230 volts Check functioning of contactor coil Check if heater is burnt or open Check if MCB has tripped due to short circuit		
Controller display shows open	Temperature sensor faulty	Check Resistance Across Sensor Terminates With Multimeter Check If sensor termainal Connection Is proper.		
Temperature exceeds set value of 121°C	Temperature controller faulty Contactor faulty Sensor faulty	Check output at terminal 5 of controller If actual temperature increases beyond set value the output of 230 Volts at terminal 5 should cut – off Check if contactor output terminals are shorted Check resistance across sensor. Check if sensor is faulty		
Material in Autoclave are not fully sterilize after completion of cycle. Temperature	Auto Air purging(in fully automatic model) or manual air purging (in semi automatic model) is not done sufficiently/properly	For fully automatic model – check if solenoid valve releases air up to a temperature of 99ºC For manual model – check if manually the steam release valve is kept open up to temperature of 99ºC to enable exhaust of hot air		

non uniformity observed within chamber. Pressure gauge shows high pressure while temperature controller maintains 121º C. accurately		from chamber		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Verification 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
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Sign/Date: ……

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

Inference:

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

8.6 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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9.0 REFERENCES:

- Design Qualification Party Document
- Installation Qualification Party Document
- Operation Qualification Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- 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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16.0 ABBREVIATIONS:

AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practices
FFS	:	Form Fil Seal
mm	:	Millimeter
MOC	:	Material of Construction
NOS	:	No of Strength
Nos.	:	Number
OQ	:	Operational Qualification
Pvt.	:	Private

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)			
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HEAD (PRODUCTION)			