DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VERTICAL AUTOCLAVE

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

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

PROTOCOL CONTENTS

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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 prepare the Design Qualification document for Vertical Autoclave on basis of Design Qualification document given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Vertical Autoclave.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings provided by Vendor shall be verified during Design 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	• Preparation, Review Authorization and Compilation of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production &Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Quality Control	• Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of Design Qualification 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 Required. ➢ Identification of components for calibration ➢ Brief Process Description ➢ Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

5.0 PROJECT REQUIRMENT:

- To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented. The Vertical Autoclave its associated components are designed in accordance with cGMP principles

6.0 BRIEF PROCESS 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.

6.1 OPERATIONAL USER REQUIREMENTS

- Meets required temperature condition, attains 121°C as per ICH guidelines and FDA regulations
- Controls and continuously maintains temperature of 121°C within permitted tolerance.
- Produced in a facility that is ISO 9001:2000 certified and which has a formal Quality Management System
- Calibrated prior to delivery vs. generally accepted standards.
- Has service maintenance arrangement at regular frequency.

6.2 OPERATIONAL MANUFACTURERS REQUIREMENT

- Constant stabilized voltage supply of AC 230 Volts 50 Hz
- DM or Distilled water for heating / steam generation
- Annual Maintenance Contract

When switched ON the display shows the following screen for 5 seconds

OSWORLD AUTOCLAVE
LOGGER & CONTROLLER

Assuming all connections are proper, the process screen is displayed as follows.

SP : 121.2 C 020 min **PV: 30.5 C 000 min**

Unless the logged data is printed, the process cannot be started. This ensures that the last cycle's data is not inadvertently lost. Press the PASSWORD key to print. Ensure that the printer is ON and the baud is set properly. After the data is printed, the process screen shows as follows

A : 00 psi B : 32.0 **C: 32.0 D : 32.0**

Zone–A is used as reference for control. The system is in idle state now. Air purging relay is ON and is indicated on the LED.

To start the batch, press START / STOP key (to terminate the batch, press this key again.) . The process screen alternatively toggles between the above screen and the following one:

SV : 121.2 PV : 82.0 **H E A T I N G**

The HEAT LED glows and shows the status of the Heater. Meanwhile, when the factory set Air Exhaust temperature is attained, the Air Exhaust relay is put OFF Once the control set point (Set 1) is reached, the following screen is displayed

SV : 121.2 B : 121.2	**S T E R I L I Z I N G 30**

The proportional action ensures that the process temperature is controlled at or above the Set value. The value on the right corner of the second line is the remaining sterilizing time in minutes. Once the Sterilization Time has elapsed, the Heater is put OFF and the Air Exhaust relay and the buzzer comes ON indicating that the sterilizing time is over.

E X A U S T

To acknowledge the buzzer, press the P / ALM ACK key.

Air Exhaust relay is ON till the temperature reaches 99.9 8C after which the buzzer (if not acknowledged) and the Air Exhaust relay is OFF. The display shows:

SV : 121.2 PV : 99.9	**END OF CYCLE**

The batch process is over. Audio and Visual indications are also provided for the following: -

a) Water Level LOW
b) Sensor Open / Polarity
c) Cycle Over

To acknowledge the audio alarm, press the ACK button.

SETTING THE CONTROL SET POINTS:

1. Press PROG key. The display shows

STER TEMP (deg C) 121.0

The present set point is displayed on the second line.

2. Press UP or DOWN key to increment or decrement this set point or go to step 3.

3. Press ENTER key to save the new set point. The display now shows
4.

STER TIME (mins)

5. Press UP or DOWN key to increment or decrement this set point or go to step 5.
6. Press ENTER key to save the new set point. The display now shows

Date (MM:DD)
0 5 : 2 8

6. Press UP or DOWN key to increment or decrement this set point.(Note: The range is from 01:01 – 12:31.) OR go to step 7.

7. Press ENTER key to save the new set point. The display now shows

Time (HH:MM)
2 1 : 1 0

8. Press UP or DOWN key to increment or decrement this set point.(Note: The range is from 00:00 – 23:59.) OR go to step 9.
9. Press ENTER key to save the new set point. The display now shows

Year (YYYY) 2 0 0 7

10. Press UP or DOWN key to increment or decrement this set point.(Note: The range is from 2000 to 2999.) OR go to step 11.

11. Press ENTER key to save the new set point. The display now shows

Baud rate
19200

12. This is the rate at which data is sent to the serial printer. The baud at both ends of the communication should be the same. Press UP or DOWN key to increment or decrement this set point.(Note: The range is 1200,2400,4800,9600 or 19200) OR go to step 13.

13. Press ENTER key to save the new set point. The display now shows the process screen.

NOTE: To print the previous cycle on a serial port of the dot matrix printer, press the P key. The sterilization data is printed.

SETTING THE FACTORY SET POINTS:

Note: Press DOWN and ENTER keys together for factory settings

14. Press the PROG key. Proceed as per above section till step 13. The following screen is displayed.

Purge Set 98.0

15. This is the temperature at which the Air Purging relay is put OFF during heating. Press UP or DOWN key to increment or decrement this set point (The range is from 90.0 to 110.0 8C). OR go to step 16.

16. Press ENTER key to save the new set point. The display now shows

Cyc time (secs) 5.0

17. This is the proportional action cycle time. Press UP or DOWN key to increment or decrement this set point(The range is from 0.1 to 9.9 secs). OR go to step 18.

18. Press ENTER key to save the new set point. The display now shows

Control offset - 6

18. If this set point is set to 0, then at zero error (PV = SP), the control power output is 50 %. To increase or decrease the power, increase or decrease this value respectively. Press UP or DOWN key to increment or decrement this set point(The range is from -16 to +16). OR go to step 20.

19. Press ENTER key to save the new set point. The display now shows

Offset 0 . 0

20. This set point is changed to correct any inaccuracies in the sensor. Press UP or DOWN key to increment or decrement this set point. (The range is from –5.0 to +5.0 8C).

21. Press ENTER key to save the new set point and exit from set mode. The display now shows the process screen.

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on Design and Process requirement for the manufacturer of equipment ensures complies with Design and Process requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Equipment Parameters:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application:	All the loaded articles and supporting accessories should be sterile after performing the validated cycles.	Process Requirement
Working:	During Steam Sterilization, Steam distribution should be uniform in the chamber.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Switch.	Design Requirement

8.2 Utility Requirements/Location Suitability:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	• Voltage: 230 ± 10 % V AC • Phases: 1 Phase • Frequency: 50-60 Hz	cGMP Requirement
Room Condition	Should be able to meet the requirement of clean environment.	Process Requirement

8.3 Technical Specifications/Key Design Features:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Manufacturer	Osword	Design Requirement
Model	QAT-G-175	Design Requirement

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Capacity	175 Ltr.	Design Requirement
Sr.No.	2964	Design Requirement
Inner Chamber Dimension	22 x 30 Inch	Design Requirement
Operating Voltage	:230 ± 10 % V AC	Design Requirement
Analog Input	2 Nos.PT.100 – 3 wire	Design Requirement
Range	0-150 ° C	Design Requirement
Indicating Accuracy	+ /- 0.1 ° C	Design Requirement
Control Accuracy	: +0. 5°C	Design Requirement
Control Output	SSR drive output	Design & process Requirement
Purging output	1 C/O Relay content (230 / 3 A)	Design & process Requirement
Alarm output	Peizo- Electric Buzzer Compatible O/P	Design & process Requirement
MMI	16 x 2 LCD Panel, 6 Key Membrane Keypad.	Design & process Requirement
Printer Port	RS232 Serial Interface with Programmable baud (1200 to 19200)	Design & process Requirement
Heater Coupling	1 ¼ ” BSP Qty : 2 Nos	Process & Safety Requirement
Wheel	Caster Wheel Qty : 4 Nos	Process & Safety Requirement
Coupling on the Lid	¼ ” BSP Qty : 4 Nos	Design Requirement
Solenoid valve Coupling	Make : Avcon ½ ” BSP Qty : 1 Nos Function : Release air / Steam shut at 95 to 100 °C	Design Requirement

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Temperature Sensor Coupling	3/8 ” BSP Qty : 1 Nos Type : PT-100 Sr.No. 2851 /1215	Design Requirement
Drain Coupling	3/8 ” BSP Qty : 1 Nos	Process & Safety Requirement
Ring/ Stud	3/8 ” BSP MOC : SS Brakelite	Process & Safety Requirement
Slotting on lid & Flange	6/8/12 No.	Design Requirement
Chamber Joint grinding Finish	Mirror Finish	Design Requirement
SS Bracket Size	STD	Design Requirement
SS Bracket Stand	STD	Design Requirement
Door Silicon Gasket Fitting	Joint less	Design Requirement
Pressure Gauge	¼ ’’ BSP 30 PSI	Design Requirement
Steam Release Valve	¼ ’’ BSP SS Type : open / shut	Design Requirement
Safety Valve ¼ ’’	¼ ’’ BSP Spring Loaded open at 18 PSI Function : High Pressure Control Sr.No. 1603163	Design Requirement
Timer Function	Set at 20 minute check cut-off	Design Requirement
Safety Temperature Sensor 3/8 ’’ BSP SS	Type : PT -100 Sr.No. 2960/021C	Design Requirement
Heater Breakdown Test	1.2 kw /10 sec	Design Requirement
Circuit Breaker	Type : 16/25 amp TC Make : Hogger	Design Requirement
Control Panel Wiring	Crimped / Tied	Design Requirement
Power Consumption	Running Power	Design Requirement

8.4 Material of Construction:

S. No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Body	SS 304
2.	Inner Body	SS 316
3.	Gauge	BSP
4.	Ring	SS Bakelite
5.	Basket Stand	SS

8.5 Safety:

S. No.	Parameters	Safety / Interlocking Provision	Reference
1.	Electric Safety	MCB Circuit Breaker for overload and short Circuit Protection	cGMP Requirement
2.	High Pressure Safety	Spring Loaded safety valve set above working pressure release	Safety & cGMP Requirement
3.	High Temperature	Provide in fully automatic model only . safety Temperature controller cuts off heater in case Temperature exceeds set valve with audio buzzer Indication.	Safety & cGMP Requirement
4	Low Water level cut off	Provide in fully automatic model only- cuts off power to heater incase Water level in Chamber drops.	Safety Requirement

8.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Vertical Autoclave	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowledge, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

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

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Purchase Order Copy.
- Any other relevant documents.

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
GA	:	General Arrangement
Hz	:	Horse Power
IB	:	Injection block
Ltd.	:	Limited
mm	:	Millimeter
MOC	:	Material of Construction
Pvt.	:	Private
QA	:	Quality Assurance
SS	:	Stainless Steel
V	:	voltage
VLA	:	Vertical Autoclave
W	:	Watt

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			