USER REQUIREMENT SPECIFICATIONS

OF

PHOTOSTABILITY CHAMBER

PHARMA DEVILS

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1. PREPARATION & APPROVAL SHEET:

Prepared by

Name	Signature	Date	Department

Checked by

Name	Signature	Date	Department

Approved by

Name	Signature	Date	Department

2. LIST OF GENERAL COMPONENT:

S.No.	Description
1.	Main Cabinet
2.	Main switch
3.	PLC
4.	Power Supply Plug
5.	ON/OFF Switch
6.	Compressor
7.	Heater
8.	UV Light

3. GLOSSARY:

Abbreviation	Description
URS	User requirement specifications
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
SS	Stainless Steel
HP	Horse power
MOC	Material of Construction
EU	Europe Union
PLC	Programmable Logic Control
^{0}C	Degree Celsius
MM	Millimeter
RTD	Resistance Temperature Detector
MOC	Material of Construction
SS	Stainless Steel

4. TECHNICAL:

S.No.	Parameters	Required Specifications
4.1.	**General**	
1.1	**Description**	Photostability Chamber
1.2	**Use**	Storage of stability Samples.
1.3	**Field Identification**	Stability Area
4.2.	**Salient Features**	
4.2.1	**General**	(i) Unit to be compact with ease of operation. (ii) A closed system with consistent performance. (iii) Ease of maintenance (iv) Easily cleanable with minimum recesses and crevices. (v) All welded joints to be grinded where product may be in contact to smooth finish and lead free. (vi) All gaskets provided to avoid leakages should be amendable for easy removal and re-fixing, (vii) All electrical / pneumatic parts should be pre wired. (viii) Convenient lubrication design (ix) Complete safety interlock design (x) All bolts, nuts on the exterior part of equipment to be preferably with cap head or cap nut. (xi) Parts which are required for cleaning should be provided with quick fixing arrangement.
4.2.2	**Material of Construction**	SS304/SS 316 L
4.2.3	**Finish**	Visually good
4.2.4	**Electrical Construction**	Non flameproof / flameproof.
4.2.5	**Lights**	UV and Fluorescent Light
4.3	**Operational requirements**	
4.3.1	**Capacity**	Internal Size : 630 (W) X 600 (H) X 600 (D) mm External Size : 790 (W) X 1285 (H) X 895 (D) mm
4.3.2	**Control Parameter**	1. Temperature: 15^{o}C to 60^{o}C. 2. Temperature uniformity: +1^{o}C.
4.3.3	**Desired Accuracy**	1. Control temperature accuracy: +0.2^{o}C.

S.No.	Parameters	Required Specifications
4.3.4	**Control**	Programmed Parameters: fully controlled by programmable logic controller (PLC) and communication on Ethernet.
4.3.4.1	**Data & Security**	YES
4.3.4.2	**User interface with supervisors and operators for the control platform** **Interface with other Equipment and system**	NA
4.3.4.3	**Security level**	3 Level Password Protection
4.3.4.4	**Data collection**	Programmable logic controller (PLC) base unit with Ethernet port of communication with software for data acquisition system complying with 21 CFR part 11.
4.3.5	**Component Reference details**	YES
4.3.6	**Functional Requirements**	**PLC program feature:** 1. Version information. 2. Safety features. 3. Auto change over to stand by system (If present). 4. Manual change over from HMI (If present). 5. Compressor changeover due to HP and LP alarm. 6. PLC IP address setting from HMI. 7. Settable change over time from HMI. 8. Different password protection for set value and calibration mode. 9. Data recording whenever PLC supply is switched ON.
4.3.7	**Alarm System**	Audio and visual alarms generated for temperature variation and utility failures. 1. Temperature deviation. 2. Utility failure. 3. Emergency alarm for man trap in side of BOD Incubator
4.3.8	**Power failure / recovery**	In the event of a power failure, the system shall protect product against damage. The system will stop in a safe mode automatically upon loss of electricity, air or other major utility and will require operator intervention to re-start.

S.No.	Parameters	Required Specifications
4.3.9	**Emergency stop**	The emergency stop mechanism(s) shall be provided.
4.4	**Utilities**	Supplier to give details and drawings for exact size, location, type, capacity etc. of the utilities required.
4.5	**Maintenance**	Supplier should provide the following maintenance instructions. • Operation and Maintenance manuals along with as built drawings • Daily checks on machine Cleaning procedures
4.6	**Inspection and Testing**	• Traceability of materials certificates indicating lot numbers and other related information. MOC Certificates, Test/Calibration certificates of all critical and non-critical components
4.7	**Commissioning and Documentation**	• DQ/IQ/OQ/PQ to be completed by the supplier along with representatives. • The Supplier to demonstrate the Performance of the machine at User site as per agreed terms. • Material of construction Certificate (MOC) of Contact Parts / Non-contact parts. • Calibration Certificates traceable to NIST standard. • Performance Test Certificates. • Operation and Maintenance Manual
4.7.1	**Development**	The Supplier shall provide a Project Manager for the project to provide a single communication point with the User.
4.8	**Training**	Supplier to train the respective technical associates on operation, maintenance and cleaning of the equipment wherever applicable.
4.8.1	**Start up support**	Telephone / Fax / E mail ID / Address
4.8.2	**Post start up support**	Replacement parts availability list (normal lead times shall be listed) System improvements (supplier shall notify user of any improvements)
4.9	**Packaging**	Supplier to specify packaging of machine for safe transportation and delivery at the site.
4.10	**Deviations**	Any deviation from URS shall be highlighted
4.11	**Delivery**	As per Purchase Order