USER REQUIREMENT SPECIFICATION

Name of Item: BOD Incubators	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 1 of 8

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Issued to mfg / supplier by purchase department _____

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Name of Item: BOD Incubators	**Protocol No.:**.....
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1 Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2 Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3 Purpose:

The objective to prepare URS for BOD Incubators is
--To set the guideline for selection of BOD Incubators for intended use
--To ease the selection process
--To provide a specification to the vendors for there submission of techno commercial offer.

4 Scope:

This document is applicable for BOD Incubators intended to use at manufacturing site.

5 Specifications:

5.1 Description of Equipment/System:

The BOD Incubators must be designed in such a manner that it allows precise, standard compliant simulation of all climatic conditions **under a constant atmosphere** for carrying out all long duration storage for durability and stability tests according to the internationally valid EN standards and current pharmaceutical ICH guidelines Q1A & Q1B.
The temperature technology must give unsurpassed temperature accuracies and reliably avoids the occurrence of condensation.
The equipment must comply to GLP regulations, should give germ free and drift free humidity, must be easy to clean and low maintenance Machine should meet all cGMP and GEP standards, and comply CE safety and electrical standards. Machine needs to run continuously in fully automatic mode.

Case	Storage condition
For Semi permeable containers	30°C and 35% RH
	40°C and 15% RH
Photo stability chamber	- Light source D65 -Temperature 25 ° C

5.2 Identification number and location:

Equipment Name	Identification Number	Location
Stability Chamber	…..	Stability room
Stability Chamber	….	Stability room
Stability Chamber	….	Stability room
Stability Chamber	….	Stability room
Stability Chamber	….	Stability room
Stability Chamber	….	Stability room
Photo stability chamber	….	Stability room

5.3 Intended use:

The equipment must be designed to work continuously for 3 shifts per day on daily basis.

5.4 Intended type of material to be handled:

This will include handling of drug products like injectables (Dry powder and liquid i.e. SVP) and ophthalmic products packed in semi permeable containers.

5.5 Construction:

Interior made of stainless steel SS 316
Exterior made of stainless steel SS304
Perforated stainless steel shelves (SS304)
Proper insulation with non-shedding material.
Door shall be provided with lock and key.
Safety devices including mobile messages.
Internal lighting
Water level sensor with audio/visual alarm
Proper Internal lighting.
Validation port.
Double Insulated doors and preferably door closer with gasket

5.6 Capacity:

The internal dimensions / capacity of the stability Chamber shall be approximately.

Equipment ID No.	Capacity	Storage conditions
…..	~1000 L	30 ° C and 35 % RH
…..	~1000 L	30 ° C and 35 % RH
…..	~1000 L	30 ° C and 35 % RH
…..	~1000 L	40 ° C and 15 % RH
…..	~1000 L	40 ° C and 15 % RH
…..	~1000 L	40 ° C and 15 % RH
…..	~300 L	40 ° C and light D 65

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440VAC, 50 Hz, 3Phase. Cabinet enclosure – protection category will be IP54 / IP55.

5.8 Control parameters:

Temperature and humidity accuracy and uniformity within the chamber.
Light and temperature in case of photo stability chamber.

5.9 Acceptable tolerance for control parameters:

Parameter	Range	Criteria
Temperature	30 to 60 ° C	± 1.0 °C
Relative Humidity	05 to 80 % RH	± 3% RH
Light Illumination (For photo stability chamber)	Not less than 1.2 million lux hours Ultraviolet energy of not less than 200 watt hours/square meter Temperature 25 ° C	Not less than specified.

5.10 Type of control System:

1. Technology that guarantees unsurpassed temperature accuracies and should avoid condensation preferably with dehumidification system.
2. Microprocessor based PID control for temperature and Humidity
3. For storage condition below 40% RH, dehumidification system to be provided.
4. Auto defrosting device
5. Refrigerant used for cooling system must be CFC free and eco friendly.
6. Humidification system must provide aerosol free and germ free humidity.
7. Sensor used for measurement of low RH condition must be capable enough to sense the proposed range (For e.g 5% to 80 %RH).and sensor range to be provided.
8. Safety cut off in case of Overshoot/Undershoot and audio/visual alarm (Chambers will be placed on first floor and alarm has to be placed at ground floor)

5.11 Feasible parameters to be set:

Temperature, Humidity, Time interval for recording data.
For photo stability chamber light intensity to be controlled

5.12 Parameters to be indicated by control systems:

1. Temperature, humidity set value and actual value.
2. Time and date formatting.
3. Overshoot/Undershoot message and audio/visual alarm.

5.13 Available utilities:

Purified water or raw water
Electric power

5.14 Limitations / Constraints:

Height of the stability chamber shall be less than 3 meters.
Only GMP model is required.

5.15 Regulatory requirements:

1. Equipment must be complaint with internationally valid EN standards and the pharmaceutical ICH guidelines Q1A and Q1B.
2. Software must be complying with 21 CFR part 11 regulation of USFDA.

5.16 Delivery Address:

……

6 Safety:

Alarms and interlock.
Safety thermostat for over temperature.
Safety device including mobile messages
Temperature indicator cum controller,
Proper equipment earthing shall be provided.
Wiring on the machine and in the control cabinets shall be terminated at both ends and match the numbering shown in the documentation.
Safety cut off
Water sensor Alarm incase of low water level.

7 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

Normal wear parts

Parts that are easily broken

Parts that can wear out, and are long lead time availability.

Electronic components those are not readily available from a local source to the User.

The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

7.2.1 Start-up Support

Start-up support shall consist of 2 weeks of full time assistance on the User's site for installation, start-up and commissioning.

7.2.2 Training

User training shall consist of equipment training by a qualified trainer.

Certificates of training shall be provided for each person completing the training program.

7.2.3 Post Start-up Support

Post start-up support shall consist of User site visits for a period of 1 year after the completion of commissioning activities as and when required.

7.2.4 Technical Support

Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

8 Documentation:

S.No.	Document	Mode
1.	Design Specification	Paper or .pdf
2.	Controls Test	Paper or .pdf
3.	Operator, Maintenance and Service Manuals	Paper or .pdf
4.	Process and Instrumentation Diagram (P&ID)	Paper or .pdf
5.	Instrument Listing	Paper or .pdf
6.	Control Schematics	Paper or .pdf
7.	Calibration certificates	Paper or .pdf
8.	Control Panel Assembly Drawings	Paper or .pdf
9.	Machine Assembly Drawings	Paper or .pdf
10.	Bill of Materials	Paper or .pdf
11.	Spare Parts List	Paper or .pdf
12.	Validation documents	Paper or .pdf

9 References:

- cGMP and GEP regulations.
- ICH Guidelines.
- ASME and 3A.