### **KNOWLEDGE CENTRE**

#### **GUIDELINES FOR SELECTING THE EQUIPEMENT FOR LABORATORY...**

When you're in the process of purchasing one of our products, you will be able to select between several accessories that will be added to the quotation. While all these accessories are optional, it is important to define your requirements and select the appropriate additions. To help customers understand the benefits of certain accessories, follow the basic guide below.

#### First, it's important to ask yourself some basic questions:

Is the incubator to be used for general application, where audits are not critical, or do you need it for more stringent needs? Or is the EQUIPMENT required to adhere to FDA audits?

Information below will aid you when deciding which accessories to select, and for more details you can email us on <a href="mailto:rivotek@hotmail.com">rivotek@hotmail.com</a>

#### While choosing accessories for a product, the following factors should be considered:

**Size / Capacity**: RIVOTEK manufactures instruments in various capacities. The sample quantity to be tested will determine which capacity of equipment is suitable. When you do the sample, keep in mind that test conditions, for long term or accelerated study, are conducted over prolonged time durations. Customers are always advised to buy a bigger capacity than required to ensure samples have sufficient space. It is worth noting that equipments can only be filled with sample sizes up to 70 per cent of their overall capacity. Ensure your chosen equipment size has enough free space around the sides to allow air to flow freely.

Caution: Restricting or blocking air could result in some samples not getting desired exposure to set climatic conditions; this could call for a retest by an auditor.

**Test Condition**: Before purchasing, determine the temperature that your sample needs for its test. To find the optimum test condition, check the ICH guidelines to see testing standards across climatic zones. it is important to specify your TEMPERATURE test conditions when ordering a product. Only with this information can we test the respective equipment extensively based on your temperature conditions.

Single Point Data Logger: ICH guidelines mandate the presentation of documented evidence for all our thermal equipments test cycles. All information must be retained, including the difference between set values and process values during the test cycle. With this information, auditors can inspect the data properly. For many customers, data storage and logging devices becomes a vital accessory that avoids plenty of time and effort.

#### Software 21 CFR Part 11 complaint:

All electronic documentation submitted during audits must be compliant with the 21 CFR Part 11 regulatory frameworks. We strongly recommend choosing this accessory during your purchase because it provides a more efficient and convenient data management solutions.

## GENERAL FAQ ABOUT SELECTION OF LABORATORY OVENS & INCUBATORS

#### Q1. How do I purchase the Equipment?

Select the Capacity, Model available with the desired Option and send us the enquiry so that we can provide you with our best offer.

#### Q2. What capacity should I select?

One should select the capacity of the equipment considering the volume of the samples to be tested and the space available with you to install the equipment.

- **a)** In case you are the first-time user / new project with a less volume of samples it is recommend to select minimum volume in ltrs to start with. If you expect an increase in the volume of samples to be tested, then we strongly recommend maximum volume in Ltrs that is generally used in the Industry.
- **b)** In case you have large volume of sample to be tested you can ask us for technical help with respect to the requirement.

#### Q3. How much floor space is required to install a thermal chamber?

The chambers are specially designed to occupy minimum floor space with vertical structure. Floor space required for the chamber varies as per the model selected. Normally the space required for each chamber is its external size + 2 feet working space around the chamber.

#### Q4. How do I select the model?

We provide two models

STD - which is made of, Inside S.S.304 and Outside Powder coated

**GMP** - which is made of Inside S.S.316 and Outside S.S.304. If the installation environment is highly corrosive, then it is recommended to select the GMP model. Also the GMP model does not require any painting or maintenance since the entire body is made up of Stainless Steel, which guarantees a life of more than 15 years. You can select any of the two Models since apart from the material of construction all the other features and specification are same.

#### TECHNICAL FAQ'S on LABORATORY OVENS & INCUBATORS

#### Q1. What is the adjustable height of tray?

The Chamber height of each tray is adjustable at every approximate 6". Each tray can be removed and placed as per the height of the test samples.

#### Q2. What is the size of each tray?

The size of each tray varies as per the capacity of chamber. The approximate tray size is the inner size, length & breadth of the chamber

# Q3. What are the max. no. of trays that can be accommodated in a Hot Air Oven chamber? HOT AIR OVEN & BACTERIALOGICAL INCUBATOR CHAMBER DETAILS:

The maximum no. of trays that can be accommodated varies as per the capacity of chamber which is as follows:

Chamber size in cms	Capacity in Ltrs	Max No. of trays
14 x 14 x 14	42 Ltrs	2
18 x 18 x 18	90 Ltrs	2
18 x 18 x 24	120 Ltrs	3
24 x 24 x 24	215 Ltrs	3
24 x 24 x 36	324 Ltrs	3

#### **BOD INCUBATOR CHAMBER DETAILS:**

The maximum no. of trays that can be accommodated varies as per the capacity of chamber which is as follows:

Chamber size in cms	Capacity Ltrs./Cu Ft.	Max No. of trays
45 x 45 x 60	120/04	2
60 x 60 x 60	200/08	2
60 x 60 x 90	324/12	3
60 x 60 x 125	450/16	4
80 x 100 x 125	1000/35	5

#### Q4. What is the max. load recommended for each tray?

Max. Load recommended for each tray is up to 5 kg.

#### Q5. What refrigerant is used?

The refrigerant used is R134, which is CFC Free refrigerant.

#### Q6. What is CFC Free?

CFC free means Chloro Flouro Carbon free i.e. it's an Eco friendly refrigerant, which is an ingredient in the refrigerant gas, which causes damage to ozone layer, and hence it is banned worldwide.

#### Q7. What is the water drain system? Pressurized or unpressurized, details?

The drain line should be provided at the ht. of 2" from the floor level. The drain is not pressurized and is by gravity only. The drain line should have  $\frac{1}{2}$ " nozzle fitted to fit in rubber pipe.

#### Q.8. What is the heat emission behaviour of the chamber, around in the area?

The heat emission around the chamber (compressor / condenser) will be around 60 watts. It is advisable to keep the chamber in a well-ventilated room 'OR' in an air-conditioned room.

#### Q9. In what way our controllers are superior to other make controllers?

Our Microprocessor based PID controllers are very accurate and reliable and give an accuracy of  $\pm$  0.2 deg. C. for temperature. The controllers being Indian brand are most compatible with imported controllers used on any Imported Brand of Chambers. We are using the same control systems. Hence, we can confidently claim that the performance of the chamber is equivalent to any other make (Imported) chambers. These are standard controllers and manufactured in millions in quantity and are also available in any Country, taking care of replacement or possible repairs.

#### Q10. What is a Safety Controller?

A safety controller is provided on the control panel which will cut off the mains supply giving audio visual alarm in case the inside temperature overshoots or undershoots the set temperature by 5 deg. C.

The safety controller is fitted with separate Input (sensor) and a separate output and has no connection with the PID controllers used to control the temperature and humidity conditions. Also the controller will cut off the mains supply in case of set temperature variations, which safeguards the heater and avoids spoiling of the samples. It also saves time in Re-testing, as the time is very valuable for launching the product.

**Q11.** Whether audio / visual alarms are available if set conditions are crossed / not reached? The chamber has been provided with a dedicated safety controller which will cut off the mains supply in case of overshoot or undershoot of temperature by 5 deg. C. giving audio (hooter) alarm.,

#### Q.12. What is the current consumption at each of the ICH conditions, separately?

The current consumption of each ICH condition will be 12 amps for each chamber. Any chamber can be used for any conditions.

#### Q.13. What is the power supply requirement of a chamber?

The power supply required is 230 V AC 50 Hz single phase Stabilised power supply with MCB fitted for each chamber. The socket should be 5pins 20-amp plastic socket

#### **POST INSTALLATION RELATED FAQ**

## Q1. Does RIVIERA provide Warranty for its Equipment? If "Yes" than what is included in the warranty?

RIVIERA provides One year Warranty for each of the Equipment. But in the event of Complaints arising out of mishandling or through ignorance, negligence or resulting from accidents, attempted repairs, inadequate power supply, and fluctuation in voltage and improper maintenance, the warranty would not be applicable.

#### Q2. Does RIVIERA install their equipment?

RIVIERA is committed for the installation of the equipment, which includes the Training for the end user.

#### a) CALIBRATION PROTOCOLS...

- 1. Before confirming the requirement, the user should clarify all documentation aspects.
- 2. If any additional documents are required by the user, then please check the possibility of getting the same with Riviera H.O, Mumbai.
- 3. We provide calibration certificates only for GMP instruments along with IQ, OQ & PQ documents and not for Standard Models.
- 4. Calibration for Standard Model, if required by the customer, is done at extra cost & the order should be placed accordingly.
- 5. Once the instrument is dispatched from our site, we will not be able to provide any further certificates relating to calibration.
- 6. We do the calibration of the relevant components e.g. Temperature Controller, Safety Controller, Temperature Sensor & RPM Indicator etc
- 7. We get the above mentioned components calibrated from a NABL Accredited Laboratory

#### b) VALIDATION PROTOCOL, and what do we offer to the end user...

- 1. The onsite validation service is followed by IQ, OQ, and
  - PQ Documentation is provided only for GMP equipments.
- 2. Only GMP models will be provided with calibration certificate with IQ, OQ and PQ documentation. Onsite Validation <u>charges</u> will be extra (POR)
- 3. Performance Qualification with Temperature Mapping on site.
- 4. We have our standard Set Points of Temperature mapping, depending on the type of equipment; **the set points are chargeable per machine** at an extra cost. (POR).
- 5. The Performance Validation Test consists of one cycle at any one temperature point for a **2-hour period**. Data is collected in printed format from up to four or six different points within the chamber. Temperature uniformity is considered acceptable if the deviation is less than  $\pm 2$  °C of set temperature.
- 6. To avail of the above ONSITE VALIDATION service, it should be intimated in the purchase order with the user defined temperature mapping cycles

#### Q3. What do I do to install the Equipment?

RIVIERA has its Sales and Service Staff located at different regions, and will communicate with you to complete the installation process.

#### Q4. Are Spares available for the RIVOTEK Equipment?

RIVIERA provides all the necessary Spares as and when required. One can avail of the same by just sending the enquiry. It is recommended to keep the necessary spares in case of emergency / breakdown.

#### Q5. Does RIVIERA provide the revalidation and calibration service?

RIVIERA can provide the Re-Validation and Calibration service after the warranty period is over. To avail of the service, one can contact through email on (<u>rivotek@hotmail.com</u>) at our Mumbai based head office (INSTRUMENT DIVISION)

#### Q6. Who do I Contact for servicing RIVOTEK Equipment?

You can contact through email on (<u>rivotek@hotmail.com</u>) at our Mumbai based head office (INSTRUMENT DIVISION)

## Q7. Do you undertake the AMC/CMC of the equipment after the warranty period of the equipment is over?

RIVIERA is committed to keep the equipment working during warranty period and also after expiry of warranty period. We can offer AMC proposal assigned to keep the equipment in working condition only on customer request. One can avail of the service by sending the email on (rivotek@hotmail.com).

#### Q8. Is it worth purchasing RIVOTEK Equipment?

Yes, it is "WORTH" investing on RIVOTEK EQUIPMENT as it gives "VALUE FOR YOUR MONEY" in the longer run.

Any one, who is really serious about his/her analytical studies, will certainly select the RIVOTEK Equipment.