

## **Advantages of ELLAB Wireless Datalogger for Lyophilizer Validation.**

### **Product Temperature measurement and Simulation of the actual process :-**

During Lyophilization, it is very important to measure the core temperature of the products in various containers including vials etc. Ellab offer special flexible Teflon probes with fittings and fixtures to measure the product temperature accurately. The thin cables ( 1.8mm or 1.2mm dia) with special stoppers designed for Lyophilizers - Lyo Stoppers – help the processor to simulate the actual processing conditions and measure the most accurate data.



The Lyo Stoppers are specially designed stoppers for the validation of Lyophilization process. It simulate the actual processing conditions. The flexible probes will be safe even when the stoppers are closed during the process.

### **Minimum Displacement of products inside the vials :-**



The fitting on the Lyo Stoppers help to mount the sensors exactly at the hot spots inside the vials. The hotspot is normally about 1 to 2 mm from the bottom of the vial. It is very important to do the measurement exactly from the hotspots inside the vials.

The thin profile of the flexible Teflon sensors ( 1.8 mm or 1.2mm dia) make very less displacement of the product inside the vials, which helps to simulate the actual process conditions.

Insertion of thick stainless steel sensors into the small vials will not provide accurate measurements. Only Teflon flexible sensors can offer the simulation of the actual processing.

### **Long Process Duration :-**

The battery of the TS Pro Logger has very long life Each battery can be used for 1,000 working hours inside the Lyophilizer using single sensor and can use 500 hours when used with double sensor. The working hours means the time from the start of the logger and till it gets downloaded in the computer.

The battery is designed to function properly in extreme low and high temperatures. The battery can be replaced very easily by the users. Special cold battery for Lyophilizers is included in the offer.

Each Logger has a memory capacity of 60,000 data points in the non-volatile memory when used with single sensor. It will be 30,000 when used with double sensor.

Storage of 60,000 data points in the same session equals sampling time of :-

16 hours with 1 sec sample rate

80 hours with 5 sec sample rate

400 hours with 25 sec sample rate.

This guarantee the trouble free validation of the Lyophilizers over the full cycles.

### **Large Number of Measuring Points**

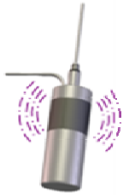
Freeze Dryer validation requires 5 measuring points per shelf – all four corners and center and batch control could require up to 1 measuring point per shelf. The offer covers all the requirements.

Ellab System handle all channels simultaneously by same receiver ( Access Point) and data “streamed” to software using proprietary transmission protocol. Loggers keep “safe copy” of data until offloaded.

### **Automation / Continuous run including SIP**

Same system cab be used for the preparation of vials, batch control as well as cleaning and validation of Freeze Dryer unit. CIP, SIP and FD validation continuously

### **RF Transmission – Online Measurement :-**



The RF transmitter can be used to view / download the online data. The loggers are equipped with RF transmitters and will be received using RF receiver.



The transmission range is upto 100 meters in open space, without having the hindrances of blocks. But when the process is performed inside closed Lyophilizer with thick stainless steel walls, the transmission range will be about 15 meters. The receiver can be placed at 15 meters from the logger and can be re-transmitted to any long distance by connecting a wireless router to the transmitter or by connecting a LAN cable.

If the lyophilizer is very large, more than 15 meters length, then more RF receivers can be used which collects and resend the signals to cover the distance properly.

The computer and reader station can be kept at the office (long distance) and can receive online date which will be re- transmitted from the transmitter after receiving it from the logger.

The signals will not be disturbed by other RF signals ( if any) or will not disturb other signals. Only one specified user will be able to receive the data, which guarantee total security to the system and data. In case the signal is lost during the transmission, it will retain the lost data immediately when the connection is retained. The data will be over written when the loggers are manually downloaded at the end of the process

### **Repeat Tests :-**

As per the standard SOPs, the SIP validation may be performed more than once ( may be 3 times) continuously, In such cases, you need not have to take the loggers out to stop the process or to re-start the process The loggers can be restarted or can do repeat tests without manually taking out the loggers from the chamber. If you want to do three repeat measurements continuously inside the chamber, then it could be possible by closing the running file and opening new profiles online.

At the end of all the processes, the user can take out the logger and stop it after downloading the files. The total data can be downloaded online as well as at the end of the process.

### **Logger with replaceable sensors.**

The offered Ellab TS Pro logger system is configured with Flexible sensors which has a temperature range from -80 to +140 deg C. But the same logger can be used for your Depyrogenation applications just by replacing the sensor with our rigid or stainless steel flexible sensors which can be used to measure temperature upto +400 deg C ( with our thermal barrier). Similarly the logger can be used to measure from -196 deg by connecting our ultra low temperature sensor.



Same Logger can be used for Pressure measurement just by connecting the pressure sensor to the loggers and can measure Humidity by connecting humidity sensor to the logger.

So the quoted loggers can be used for all your validation applications just by changing the sensors with very minimum additional expenses

### **Contact Puck**

The main problem which is being faced since a long time during lyophilization validation is the contamination of the shelves while connecting the sensors to the shelves. The flexible sensors are normally pasted to the shelves using special tapes which withstand ultra low temperature.



But Ellab had developed special accessory called “ Contact Puck “ which is made up of special grade of brass. Here the tips of the rigid or flexible probes can be inserted into the brass and can place it in the shelves. These contact pucks are sterilizable and so no contamination during the measurements.

### **Data Analysis, Data Integrity and FDA compliance**

The software is fully in compliant to FDA 21 CFR Part 11.

Data is collected and saved by using safe and quick proprietary transmission protocol. Software works with database handling from one platform. Reports are in electronic pdf format.

The package includes all the required documentation including IQ/OQ etc. Audit Trail and Electronic signature are available in the software.

### **Calibration**

It is possible to perform manual, semi automatic and fully automatic calibration. You can perform the calibration using your available oil baths / dry blocks by using Ellab master sensors.

The sensors used are Pt 1000 / Pt 2000. Hence pre and post calibrations are not mandatory for every measurements. You can perform the calibration once in a year or once in 6 months.

### **Master Sensor Calibration :-**

You need to calibrate the master sensor once in a year. TTL Technologies have NABL accredited calibration lab at Bangalore, where in you can perform yearly calibration. Along with the master sensor, you can perform the calibration of the loggers and sensors.

### **Service Center**

We have a full fledged service centre at Bangalore to support your equipment. We keep additional spares, accessories, spare batteries, stand by systems etc at our service centre, which guarantee trouble free operation of the system for a very long time.

We also offer extended warranty support and Annual Maintenance Contract for the quoted system.

### **Online Technical / Application Support :-**

We have Lyophilization Validation expert at Ellab A/S Denmark who will be pleased to provide online technical / application consultancy for any assistance related to the validation of Lyophilizes. Ellab also conducts frequent training courses on various pharmaceutical validation services including validation of Lyophilization. We welcome our customers to participate in those training courses to update themselves with the latest developments in the international pharmaceutical validation field.