

## Pharmatherm the Validation Specialists! warehouse product distribution thermal mapping solutions:

To meet with global, regulatory & ICH standards for storage, handling, and distribution on medicinal products.

Our specialist thermal mapping equipment has tracked product from Cork to Brazil, our data loggers deliver extremely precise thermal data to ensure compliance.

The distribution of temperature-sensitive medical products, pharmaceutical, life science products to provide documented evidence ensuring product quality and 'Patient Safety is Paramount'.

Warehouse thermal mapping: to gather thermal data in order to provide documented evidence that a warehouse remains within the specified temperature limits under the extremes of internal and external conditions.

Temperature & Humidity Thermal Mapping Qualifications from PharmaTherm, measure Temperature (°Celsius), relative humidity RH, MKT mean kinetic temperature.

PharmaTherm's data logging equipment is supplied by Sensitech and Vaisala our reference equipment is calibrated by an accredited UKAS laboratory and NIST traceable to national standards.

### **Calibration & Accuracy:**

Pharmatherm recommends Sensitech TempTale®4 Multi-Alarm data loggers. The unit can measure temperatures in the range -30°C to 70°C. The accuracy of the unit is  $\pm 1^{\circ}\text{C}$  from -30°C to -10°C,  $\pm 0.5^{\circ}\text{C}$  from -10°C to 45°C and  $\pm 1^{\circ}\text{C}$  from 45°C to 70°C.

The relative humidity data logger from Sensitech TempTale®4 Humidity Monitor. The unit can measure relative humidity in the range 10% to 100% RH and temperatures in the range -30°C to 70°C. For temperature readings the accuracy of the unit is  $\pm 1.1^{\circ}\text{C}$  from -30°C to -18°C,  $\pm 0.55^{\circ}\text{C}$  from -18°C to 50°C and

±1.1°C from 50°C to 70°C. For relative humidity readings the accuracy of the unit is ±4% RH from 10 to 90% and ±5% RH from 90 to 100%.

The TempTale®4 Multi-Alarm units will be issued with a 3-point calibration certificate and certificate of validation. The calibration certificate will be valid for one year from the date of issue. Pharmatherm have found the product to be extremely reliable and well supported.

**Single point calibration verification:** a check will be completed against a calibrated VAISALA HM40 humidity and temperature meter at ambient temperature. On completion of the mapping study a minimum of 10% of both temperature and humidity data loggers will be returned to the suppliers (Sensitech) for calibration verification.

A detailed verification report will be issued by Sensitech and will be used to show that the loggers remained in a calibrated state during the study period.

**How many data logger to post verify:** The IMB have recently acknowledged that a minimum of 10% of data loggers should be post calibrated following this type of thermal mapping exercise.

## MKT Explained!

MKT (Mean Kinetic Temperature) is defined by the ICH as “a single derived temperature that, if maintained over a defined period of time, affords the same thermal challenge to a drug substance or drug product as would be experienced over a range of both higher and lower temperatures for an equivalent defined period.”

In other words, MKT is a calculated, fixed temperature that simulates the effects of temperature variations over a period of time. It expresses the cumulative thermal stress experienced by a product at varying temperatures during storage and distribution.

The formula Pharmatherm use for calculating MKT is as follows:

$$T_K = \frac{\frac{\Delta H}{R}}{-\ln \left( \frac{e^{\frac{-\Delta H}{RT_1}} + e^{\frac{-\Delta H}{RT_2}} + \dots + e^{\frac{-\Delta H}{RT_n}}}{n} \right)}$$

Where,

$T_k$  = MKT expressed in °K

$\Delta H$  = Heat of activation / activation energy (83.144 kJmole<sup>-1</sup>)

R = Universal gas constant (8.3144 x 10<sup>-3</sup> kJmole<sup>-1</sup>°K<sup>-1</sup>)

T = Temperature expressed in °K

n = Total number of equal time periods over which data is collected

### Alarm Limits:

Alarm limits should be clearly defined for the purposes of a study please see an example of alarm limits below:

- MKT within warehouse should be  $\leq 25^{\circ}\text{C}$ .
- No individual temperature reading within the warehouse  $> 30^{\circ}\text{C}$ .
- No individual temperature reading within the warehouse  $< 5^{\circ}\text{C}$ .

Please note: additional alarm monitoring conditions can be set-up for the study period

### Locating Data Loggers:

The data logger locations should be chosen by means of a risk assessment. The risk assessment involves a walk down of the facility during which the following factors are taken into consideration:

- Volumes of the storage area
- Location of heating / cooling units
- Location of lighting
- Location of roof skylights
- Areas of high traffic
- Layout of racking / shelving
- Location of doors internal / external
- External walls
- Location of permanent temperature / relative humidity monitoring units
- Sun rise and fall pattern

**Service it's a pleasure for us, please don't delay and contact PharmaTherm today!**

Contact Pharmatherm for further advice on thermometric test pack setups contact us for quotation however large or small the project maybe. We aim to provide a competitive validation service. Please 'don't delay and contact PharmaTherm today' email: [info@pharmatherm.ie](mailto:info@pharmatherm.ie)

See the Pharmatherm website please log onto [www.pharmatherm.ie](http://www.pharmatherm.ie) technical/training page



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