Temptime Corporation

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- ## HEATmarker is a Mean Kinetic Temperature Indicator.

Mean Kinetic Temperature (MKT) is the best scientific way of expressing the overall effect of temperature fluctuations during storage or transit of perishable goods.

- ## How is Mean Kinetic Temperature Calculated?

Technically speaking, MKT is an expression of cumulative thermal stress experienced by a product at varying temperatures during storage and distribution. In other words, MKT is a calculated, single temperature that is analogous to the effects of temperature variations over a period of time.

MKT is not a simple weighted average. The calculation of MKT gives the higher temperatures a greater weight when computing the average than would a simple numerical average or an arithmetic mean. This weighting is determined by a geometric transformation--the natural logarithm of the absolute temperature.

By using this unequal weighting of the higher temperatures in a temperature series, MKT takes into consideration the accelerated rate of thermal degradation of materials at these higher temperatures. Therefore, MKT provides for the non-linear effect of temperature.

- ## Definition of MKT*

Mean Kinetic Temperature is defined in the international Conference on Harmonization (ICH) Q1A Documents as[1]: " 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 period. The mean kinetic temperature is higher than the arithmetic mean temperature and takes into the account the Arrhenius equation.

When establishing the mean kinetic temperature for a defined period the formula of J.D. Haynes (J. Pharm. Sci., 60:927-929, 1971) can be used."

MKT is expressed as:

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

Where:

T_K = the mean kinetic temperature in kelvin

ΔH = the heat of activation for the degradation; assumed to be 83.144kj per mol unless more accurate information is available from experimental sstudies

R = 8.3144 x 10-3 kj per degree per mole (the universal gas constant)

T_1 to T_n = re the temperatures at each of the sample points in kelvins for each time period

n = the number of temperature sample points

***** Extracts from: The Use Of Mean Kinetic Temperature (MKT) in the Handling, Storage, and Distribution of Temperature Sensitive Pharmaceuticals, R. H. Seevers, J. Hofer, P. Haber, D.A. Ulrich, R. Bishara (Pharmaceutical Outsourcing, May/June 2009).

[1] International Conference on Harmonization (ICH) Q1A(R2): Stability Testing of New Drug Stbstances And Products (Second Revision).