

New Proposed Chapter - Using Mean Kinetic Temperature to Evaluate Temperature Excursions during Storage and Transportation

Type of Posting: General Announcement

Posting Date: 26-Oct-2018

Expert Committee: General Chapters—Packaging and Distribution

Input Deadline: 26-Nov-2018

Suggested audience: Organizations and individuals involved in the storage and transportation of finished drug products that want to utilize the Mean Kinetic Temperature (MKT) calculation to better understand the impact of temperature excursions.

Estimated proposal PF: *Pharmacopeial Forum* 45(3) [May-Jun. 2019]

Background and objective(s): The extent of physicochemical degradation of drug products depends on factors such as product stability, how a product is stored, and how it is packaged. A major consequence of drug product degradation is that the product can fail to maintain its critical quality attributes. Temperature is likely to vary during the life of the product which can impact its degradation rate and stability. Mean Kinetic Temperature (MKT) is defined as the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. MKT integrates the time-temperature history and takes into account the fact that long temperature excursions at slightly elevated temperatures can be just as, or more, impactful than short temperature excursions at elevated temperatures. Thus, MKT is a way to summarize the time-history of a product's temperature exposure with a single "effective" or "virtual" temperature.

Description of scope and application: This informational general chapter will focus on the proper and improper application of MKT to evaluate temperature excursion of finished drug products as they are stored and transported.

Anticipated proposed design phase activities: *Stimuli* Article on the topic was published in *PF* 44(4) [Jul-Aug. 2018]

Anticipated implementation timing: Routine

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CN-19-018-00