

Use of a Two Tiered Degree-Hour Measure for the Management of Investigational Medicinal Product Over-Temperature Excursions Using Mean Kinetic Temperature (MKT)

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This manuscript translates the USP Pharmacopeial Mean Kinetic Temperature (MKT) into an approach that can be applied to temperature excursion management. It also describes and justifies the use of a two-tiered model that is a conservative estimate of product stability, and it is simplified through the creation of standardized evaluation tables that the end user can apply in a simplified manner. Single or multiple excursions can be evaluated by a simple arithmetic analysis (an example of which can be found at the end of the paper). Tables are provided for both USP Controlled Room and Controlled Cold Temperature excursion evaluations (CRT and CCT respectively).

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