

Thermally Accelerated Degradation and Storage Temperature Design Space for Liquid Products

By **William R. Porter** Jan 10, 2013 4:27 pm EST



Achieving stability of the drug substance and drug products is a key quality goal. Thermal stress degradation experiments are a key tool available to product development teams to achieve this goal. A storage temperature design space can be constructed based on the realization that product shelf life is dependent on storage temperature and can be measured experimentally under different conditions of thermal stress. The existence of a storage temperature design space is implicit in current stability guidelines. Thermal conditions that result in a physical change of state of the drug product bound...

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