COMPOUNDING PHARMACY

PHARMACY COMPOUNDING ACCREDITATION BOARD

DRUG STORAGE & DISTRIBUTION PRACTICES

USP General Chapter <1079>, Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products, provides information on good practices for the storage and transportation of finished drug products.

Listed below are factors that should be considered when developing a thermal package qualification protocol, according to USP <1079> guidelines.

Factors to Consider	Comments
Transportation temperature profile for the shipping lane(s).	Typically, summer, winter, etc. Sometimes seen as exact temperatures (preferred), such as <4C, 4 to 7C, 8C to 21C, 22C to 32C, and > 32C.
Delivery cycle time, accounting for reasonable delays due to weather, traffic, or customs.	How many hours do you want to validate? Many companies set 36 hours as their minimum.
Testing beyond the qualification time to obtain worst-case data for excursion dispositioning.	Validate your shipments for more time than it takes for the average delivery.
Seasonal changes in the environment.	Make sure your temperature profiles are set according to your shipping experiences.
Testing with actual payload, worst-case configuration, or a representative sample.	
Testing that represents the minimum and maximum payload in each package.	
Probe placement should be inside or directly attached to the product.	

Factors to Consider	Comments
Perform at least three replicate tests on a representative package containing a representative thermal payload per season.	
Allow the product payload as well as the coolant to condition before you begin testing.	Immediately packing the payload with ice from the freezer may cause it to drop below 2C.
Use a recognized standard to conduct thermal qualification.	A widely recognized standard is International Safe Transit Association Testing Standard ISTA STD-7E, Thermal Transport Packaging Used in Parcel Delivery System Shipment. There also are other standards, such as those reported in the World Health Organization's Supplements and Parenteral Drug Association Technical Reports.