

Requirements

1. A minimum of 3 months stability data at 40°C/75%RH or 40°C exists for product to be evaluated.
2. Prior to implementation of ambient shipment of a product currently shipped under defined temperature range conditions, a documented assessment confirming satisfactory (compliance with specifications) 3 month stability performance at the 40°C/75%RH or the 40°C condition is to be prepared. If available, the required stability information may be obtained from previously executed studies, protocols or regulatory filings performed on the same product formulation. If the product formulation is equivalent, the stability information may be obtained from another site or location. There is no requirement to repeat stability studies if this information is already available.
3. The documented assessment should also take into consideration any relevant distribution (e.g. typical shipping duration or anticipated maximum load temperature) or product-specific information that could impact the decision to ship under ambient conditions. This document must be approved by the Site Quality Team.

Recommendations and Rationale

An evaluation using the Arrhenius Equation was conducted to determine if stability data generated at 40°C would support the elevated temperature excursion potentially affecting the potency and/or degradation of the product during shipment under ambient conditions. As part of this exercise the humidity was not considered a factor and was solely based on temperature.

The Arrhenius Equation relates rate (k) of reaction to temperature (T) and is described by the following equation:

Figure: [The Arrhenius Equation](#)

Conclusion

This document provides the scientific and risk management assessment to demonstrate that solid oral dosage forms with acceptable (compliance with specifications) 3 month stability data at 40°C/75%RH or 40°C may be shipped under ambient temperature conditions. Additionally, it provides the requirements to implement ambient shipping for those applicable products that currently are shipped under defined temperature range conditions