

Summary - Assessment of Shipping Processes for Drug Products

Awareness of worst-case conditions, the potential for unexpected delays and product stability knowledge, for example, are among key inputs to understanding the potential for risk to product quality from shipping. Where the risk to product quality is significant, qualification of the chosen shipping process may be appropriate.

For more robust products (i.e., less environmentally sensitive, more stable products) where the risk assessment indicates that shipping does not pose significant risk to product quality, an shipping qualification study is not a value-added activity and the risk assessment is by itself sufficient documented information to establish that we have evaluated the shipping process for that product.

Knowledge of product stability is a key part of understanding the risk to product quality from the shipping process. Information about product stability can come from several sources, such as:

- Regulatory filing for a formulated DP;
- Routine, annual stability testing requirements
- Accelerated stability challenges, where the conditions used for accelerated stability testing may in some cases approximate expected worst-case limits of variability of environmental conditions approached during some phases of transit;

Environmental variations to which the product may be exposed include conditions at origin, destination, transportation hubs and throughout the transit route. Environmental profiles should be based on realistic expectations of transport conditions, developed using scientifically sound criteria. This may be done in various ways such as using review of historic data, review of published standards, or field-testing/monitoring of actual shipments including seasonal variations. Profiles should include anticipated extreme conditions that challenge the effectiveness of controlling temperature, exposure to moisture, prevention of oxidation, etc. as appropriate, with the packaging to be used.

Shipping conditions such as unforeseen transport events (such as delays), temporary storage in uncontrolled environments while awaiting the next stage of transportation, and variations in weather can expose product to conditions outside the long-term storage conditions established with the product registration.

Transportation conditions can pose several potential threats to product quality. Such as

- Temperature variation;
- Variable pressures, experienced by products shipped by air transport;

Some products require storage and transport under controlled temperature to maintain product quality. In general, use of opaque primary packaging protects susceptible products from damage due to light.

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