

## **CASE STUDY: RELEVANCE OF ASTM AND ISTA STANDARD SHIPPING SIMULATION STUDIES FOR THE VALIDATION OF REAL WORLD SHIPPING OF DRUG SUBSTANCES**

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Today's global bio-manufacturing networks require that high value drug substances transfer between traditional production centers, CMOs and offshore facilities. These transfers increasingly performed in single-use bags require a thorough validation to demonstrate their integrity and safety for the drug substances. ASTM and ISTA both provide standardized validation methods using a variety of simulated shipping hazards. These tests are qualitative by nature with simple pass fail criteria and unknown factors of safety.

The paper first describes an integrated validation approach that establishes the safety factor for the standardized test methods vs. real world shipping conditions in single-use bags. Normalized ASTM D4169 and ISTA and real shipping tests were performed using liquid filled bags in their containers. Results on vibrations and shock are discussed and compared to establish the robustness, the worst case nature and the safety factor of the standard protocol.

The author then presents the data from a 4-step qualification study using the ASTM D4169 conditions at 2 different temperatures. The study contributes to the robustness of the overall supplier qualification and provides extensive data that end-users can leverage to support their own process qualification for liquid shipping in single-use systems.