

TRANSPORTATION TESTING

Pharmaceutical products and materials can be subject to degradation and damage in the transportation environment. Simulated testing is an effective way to identify contributing degradation factors and provide direction for preventive measures to ensure material and product safety from origin to final destination.



SINGOTA SOLUTIONS TRANSPORTATION ENGINEERING AND TESTING SERVICES

Project Activities and Process Steps

- Distribution and Shipping Lane Mapping and Risk Assessment
- Cold Chain Management Process Design (if applicable)
- Packaging and Transport Recommendations
- Packout and Transport SOP Development
- Test Protocol and Simulation Profile Development
 - Primary containers with/without protective packaging, palletized formats
 - Environmental Hazards: Temperature, Humidity,
- Simulation Execution (onsite test chamber)
- Post Test Material Inspection and Product Testing

Deliverables

- Packaging Design
- Packout and Shipment Method Specifications and Procedures
- Package Testing/Mechanical Qualification
- Shipping Validation
- BLA Submission Ready Validation Documentation
- Performance Qualification

Typical Test Items

- Biologics, mAb's
- Gene Therapies
- mRNA Vaccines
- Antibody Drug Conjugates (ADC's)
- Drug Device Combination Products
- Primary containers (vials, syringes, cartridges, bottles, etc.)
- Pills/Tablets/Powders/Liquids
- Packaging materials/configurations (primary, secondary, carts, pallets, shipping containers)

