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Integrated Solutions Overview

Proposal for Evaluation and Testing of a Container Closure or Delivery System with a Generic Drug Product

#10954 • 1018

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EARLY COMPATIBILITY SCREENING

In early development it must be demonstrated to regulatory authorities that a proposed packaging system is suitable for its intended use. Initial experiments must be carried out to demonstrate that a packaging system:

- Adequately protects the dosage form
- Is compatible with the dosage form
- Is composed of materials that are considered safe for use with the dosage form and the route of administration
- Functions properly as an assembled container closure system if/when using a performance feature

West Analytical Services will conduct small scale filling for single or multiple packaging systems in support of engineering studies The systems will be filled in an ISO 5 clean room and sterile gowning and gloves will be utilized during the filling of the product to minimize any contamination.

Early Screening/gross compatibility studies between the drug product and the system at accelerated conditions are performed over an 8-week period and analyzed every 2 weeks at Time 0, 2, 4, 6 weeks and 8 weeks.

Small scale lab filling includes the following.

- Equipment Set Up
- Filling and Sealing
- Filled Container Inspection
- Additional Assembly

ANDA

With baseline data and defined Critical Quality Attributes, the packaging and delivery system is evaluated against the defined attributes as the drug product / device manufacturing is scaled up to a submission batch. West offers continued support of data requirements for your regulatory submission offering Assurance that your application meets today's regulatory standards.

ANDA studies include chemical and functional stability of the drug product and system at both room temperature and accelerated conditions over the shelf life of the product.

LIFECYCLE MANAGEMENT

Data, information, and knowledge gained in product development and scale-up are intended to support the continual improvement of the product and process. Critical Quality Attributes of drug/CCS and delivery system output requirements provide clarity & define the standards to be met in technical transfers and change control processes. ICH Q12 conveys a regulatory expectation for continuous management of a product over its Lifecycle.

West Analytical Services can further support product commercialization through any of the following:

- Device Manufacturing and Assembly
- Drug & Device Packaging solutions
- Device Serialization
- Drug handling including cold storage
- Quality control release testing
- Bridging Studies
- Support of tech transfers or change management

Further details will be outlined in Integrated Solutions proposal.