eurofins | BioPharma Product Testing

Container Testing

A critical step in understanding the biological safety and suitability of a packaging system is the ability to characterize the materials and chemicals that have the potential to migrate through the barriers of a packaging component or system, resulting in contamination or degradation of the pharmaceutical drug product altering its chemical composition or functionality.

Eurofins BioPharma Product Testing performs testing on a magnitude of packaging systems and components. There are a number of compendia procedures and FDA guidelines designed to ensure that the composition and functionality of the packaging component or system is appropriate for pharmaceutical products in various phases. We utilize these regulations and guidelines to ensure packaging systems and components meet these requirements.

Why Choose Eurofins BioPharma Product Testing?

We have more than 20 years of experience testing packaging systems and packaging components.

Our experience provides the expertise to successfully complete testing per various pharmacopeias (such as USP, JP, and EP) and client-specific test procedures.

We offer general platform methods to support a variety of testing to streamline the testing approach.

We can offer a full scope of testing to identify, characterize, and evaluate the suitability and functional properties of packaging systems and components.

Common Types of Materials Tested

Eurofins BioPharma Product Testing provides a comprehensive service offering based on evaluating the physiochemical and functional properties of packaging systems and components to satisfy industry expectations.

Plastic Materials

Our service offering extends further to incorporate a full evaluation of the elemental composition and biological reactivity and suitability of the material.

Samples Types

- Plastic Container-Closure Systems
- Plastic Resins
- Plastic Bottles and Bags
- Plastic Films and Foils
- Plastic Finished Products
- Plastic Components

We have the capability to test plastic packaging system and components of various shapes, sizes, thickness, and composition.

Test Methods and Procedures

- USP <661> Plastic Packaging systems and Their Materials of Construction
- USP <661.1> Plastic Materials of Construction
- USP <661.2> Plastic Packaging System for Pharmaceutical Use
- USP <85> Bacterial Endotoxins Test
- USP <87> Biological Reactivity Tests, in Vitro
- EP 3.1 Material used for the Manufacture of Containers
- EP 3.2.2 Plastic Containers and Closures for Pharmaceutical Use
- JP 7.02 Test Methods for Plastic Containers
- Eurofins General Platform Methods
- Client Supplied Analytical Standards/Test Procedures

Technique Highlights

- Performance Testing
  - Moisture Vapor Permeation/Transmission Rate Testing
  - Desiccant Classification Testing
- Spectral Transmission Testing
- Compression/tensil Tesing (break-loose force/Gliding force)

Rubber Materials

This scope of testing extends to include a complete service offering surrounding fitness-for-duty suitability assessments. In addition, chemical and biologically suitability of rubber closures can be evaluated using compendia test methods.

We provide additional miscellaneous services to determine the biological reactivity and biological suitability of rubber materials.

Rubber Samples Types

- Closures
- Plungers
- Tip Caps and Needle Shields
- Injection Ports
- Seal Liners
- Components in Delivery/Injectable Systems

We have the capability to test rubber closures of different configurations and compositions. This would apply to coated and uncoated rubber materials.

Test Methods and Procedures

- USP <381> Plastic Packaging systems and Their Materials of Construction
- USP <382> Elastomeric Component Functional Suitability in Parenteral Product/Delivery Systems
- USP <788> Particular Matter In Injections
- USP <71> Sterility Test
- USP <87> Biological Reactivity Tests, in Vitro
- EP 3.2.9 Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and For Freeze-Dried Powders
- EP 2.6.1 Sterility Tests
- JP 7.03 Tests for Rubber Closure for Aqueous Infusion Systems
- JP 4.06 Sterility Tests
- JP 6.07 Insoluble Matter Test for Injections
- Eurofins General Platform Methods
- Client Supplied Analytical Standards/Test Procedures

Technique Highlights

- Performance Testing
  - Moisture Vapor Permeation Testing
  - Desiccant Classification Testing
- Spectral Transmission Testing

Glass Materials

Providing information on the suitability of the glass used in packaging systems in addition to the surface and inner glass compositions supporting the packaging systems durability or elemental composition.

Glass Samples Types

- Tubes
- Vials
- Bottles
- Delivery Systems
- Syringes

Test Methods and Procedures

- USP <660> Glass Containers
- EP 3.2.1 Glass Containers for Pharmaceutical Use
- JP 7.01 Test For Glass Containers for Injection
- CCIT, Image Analyzer
- Eurofins General Platform Methods
- Client Supplied Analytical Standards/Test Procedures

Desiccants & Pharmaceutical Coils

We provide a complete evaluation of auxiliary packaging components, such as desiccant and pharmaceutical coils that are used as a supporting material in packaging system. The scope of this offering includes an assessment of the physiochemical composition, identification, and elemental composition of these materials.

Pharmaceutical Coils Samples Types

- Cotton Coil
- Rayon Coil
- Polyester Coil

Desiccant Samples Types

- Bentonite
- Calcium Chloride
- Calcium Oxide
- Molecular Sieve
- Silica Geloil

Test Methods and Procedures

- USP <670> Auxiliary Packaging Components
- Eurofins General Platform Methods
- Client Supplied Analytical Standards/Test Procedures

Technique Highlights

- Moisture Adsorption Capacity Studies
- Calcium Chloride