eurofins | BioPharma Product Testing



Container Testing

A critical step in understanding the biological safety and suitability of a container is the ability to characterize the materials and chemicals that have the potential to migrate through the container's system components, resulting in contamination or degradation of the drug product.

Eurofins BioPharma Product Testing performs testing on virtually all container types requiring evaluation, including plastic bottles, glass vials, stoppers and raw plastic (resin pellets, sheets, etc.).

Why Choose Eurofins BioPharma Product Testing?

- We have more than 15 years of container testing experience.
- We can accommodate multiple container compositions and final container configurations.
- We follow various compendia including USP, EP, and JP as well as client-specific test procedures.
- We have the capability to provide a complete scope of testing for your entire container system, including evaluation of container closure integrity.

Testing Available

There are a number of USP, EP, JP and FDA compendia procedures designed to ensure that the container composition and functionality is appropriate for pharmaceutical products in various phases. Eurofins BioPharma Product Testing utilizes these compendia methods, as well as client-supplied procedures for container analysis, including:

- Permeation Testing
- Extractables Testing
- Functionality Testing
- Identification Testing

Methods

Plastics

USP General Chapters

- <661.1> Plastic Materials of Construction
- <661.2> Plastic Packaging Systems for pharmaceutical use

Testing includes Identification, Appearance of Solution, UV Absorbance, Acidity or Alkalinity, Total Organic Carbon, and Biological Reactivity Testing for Polyethylene, Polypropylene, Polyethylene Terephthalate, Cyclic Olefins and Plasticized Poly Vinyl Chloride, as well as a Chemical Safety Assessment (Extractables Testing) that can be applied to any type of plastic.

- <670> Auxiliary Packaging Components

Includes testing of cotton, rayon and polyester pharmaceutical coils and desiccants, such as bentonite, anhydrous calcium chloride, calcium oxide, molecular sieves and silica gel.

- <671> Containers – Performance Testing

Includes Moisture Permeation Testing for bottles and blister packs, as well as UV Light Transmission Testing.

EP General Chapters

- (3.1.3) Polyolefines
- (3.1.4) Polyethylene for Containers without Additives
- (3.1.5) Polyethylene for Containers with Additives
- (3.1.6) Polypropylene for Containers and Closures for preparations for parenteral and ophthalmic use
- (3.1.15) Polyethylene Terephthalate for Containers for Preparations not for Parenteral Use



- (3.2.2.1) Plastic Containers for Aqueous Solutions for Infusion typically applied to Polyethylene, Polypropylene and Poly(vinyl chloride)

Note: EP Section 3.1 is designed for raw plastic materials in the form of sheets or pellets, and testing generally includes Identification and Extractable Testing. It can be applied to bottles if requested. In this case, certain testing may not be applicable depending on the container type. Please contact your project manager if your testing fits this description.

Note: EP Section 3.2 is designed to test the following types of plastic in container form: polyethylene, polypropylene and poly (vinylchloride).

JP General Chapter

- <7.02> Test Methods for Plastic Containers

Elastomeric Closures/Rubber Closures

Containers, including the closures, for preparations for injections do not interact physically or chemically with the preparations in any manner to alter the strength, quality or purity.

Elastomeric closures for containers used in parenteral preparations are made of materials obtained by vulcanization (cross-linking) polymerization, polyaddition or polycondensation of macromolecular organic substances (elastomers). They may be formulated from natural or synthetic elastomeric substances and inorganic and organic additives, which aid or control vulcanization, impart physical and chemical properties or color or stabilize the closure formulation.

General Chapters

- USP <381> Elastomeric Closures for Injection Includes Extractable and Functionality Testing
- EP (3.2.9) Rubber Closures for Containers for Aqueous Parenteral Preparations, for Powders and for Freeze-Dried Powders includes Identification, Extractable and Functionality Testing
- JP <7.03> Test for Rubber Closure for Aqueous Infusions includes Extractable Testing

Note: These chapters are not intended to be used with materials for closures made from silicone elastomer, laminated closures or lacquered closures. Contact your project manager if your sample fits these descriptions.

Glass

Glass containers for pharmaceutical use are intended to come into direct contact with pharmaceutical products. Glass used for pharmaceutical containers is either borosilicate (neutral) glass or soda-lime-silica glass. Borosilicate glass contains significant amounts of boric oxide, aluminum oxide and alkali and/or alkaline earth oxides. Glass is also classified as Type I, II or III based on intended use. Appropriate tests are performed based on the composition and type of glass. The hydrolytic resistance is determined by titration of the extract as the quantity of alkali released from the glass under the conditions specified.

General Chapters

- USP <660> Containers – Glass
- EP (3.2.1) Glass Containers for Pharmaceutical Use
- JP <7.01> Test for Glass Containers for Injections

Note: Type I, II or III glass may be tested by all compendia, including Light Transmission as per the USP if desired.

Instrumentation

- Infrared Spectrophotometer (FTIR) for Identification by Multiple Internal Reflectance
- Differential Scanning Calorimeter (DSC) for Identification by Thermal Analysis
- Autoclave for Preparation of Extracts
- GC/FID, HPLC/UV, TLC for Plastic Additives Testing