

# Sealing Test of Pharmaceutical Packaging Materials

During the production of biologics, some chemicals or microorganisms may migrate through the packaging material into the biologic drug and eventually contaminate the product. Understanding the safety and suitability of the packaging material are key to being able to identify these impurities. The two main methods for testing the integrity of container closures are the Dye Ingress Method and the Microbial Ingress Method (both probabilistic tests).



## Our Services

**CD Formulation** is committed to providing the latest methods to test the closure performance of final pharmaceutical packaging. We have invested in state-of-the-art instrumentation to meet the appropriate regulatory guidelines and assist you in verifying the closure of your containers, and we offer dye intrusion, microbial immersion, and microbial aerosol challenge tests. These tests have unique features for ideal applications. We can help you determine which method is best for your project.

## **Dye Invasion Testing**

The sample and positive control package are completely submerged in the dye solution. A pressure of approximately 0.5 atmospheres relative to the vacuum pressure is applied for a specific period of time to restore the sample to atmospheric pressure, and then a positive pressure of approximately 2 atmospheres can be applied for a specific period of time. The package is then compared to a sample with standard defects using a visual inspection to assess whether the sample has dye present in the package. Alternatively, a UV / Vis spectrophotometer can be used to test for the presence of dye in the solution inside the package.

## **Microbial Immersion Testing**

Generic in-house methods can be used and can be customized to meet individual testing requirements. Techniques offered include vacuum, static or microbial challenge.

## **Microbial Aerosol Challenge Testing**

We can use generic methods or customize methods to meet individual testing requirements. We also offer techniques including vacuum, static or microbial challenge methods.

## **Our Vision**

We strive to be a company that provides the highest quality package sealability testing services to pharmaceutical companies around the world.

Meeting our customers' needs and exceeding their expectations will always be our goal. We will continue to be at the forefront of innovation and apply the latest science and technology to the pharmaceutical industry through our services to advance the global medical business.

## **Why Choose Us?**

We have extensive experience in method development and testing for package sealability testing programs.

Our techniques are adapted for a wide range of package materials.

Our methods minimize the number of samples required for testing.

Source: <https://www.formulationbio.com/sealing-test-of-pharmaceutical-packaging-materials.html>