



Cosmetic Preservative Efficacy Testing

The Cosmetic Regulation (EC) No. 1223/2009 stipulates that products should be safe under normal or reasonably foreseeable conditions of use. Therefore, meeting the pass criteria for Preservative Efficacy (Challenge) testing ensures the product will stay preserved until opened if it is within its expiry date. This forms a standard part of the process to get a product compliant within Regulatory requirements and in the market place.

There are a number of methods for Challenge testing, with the most commonly used and accepted being ISO 11930 Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product. Other methods include the European, United States and Japanese Pharmacopeia methods, all of which can be carried out by MSL.

In cases where the product is to be used by vulnerable populations or on sensitive areas of the body, then the Pharmacopeia method EP5.1.3 Preservative Efficacy Test (Pharma Challenge Test) is often employed, as it is a more stringent method. It should be noted that factory isolates should also be included in the Challenge test to ensure that the preservative system is effective on the microorganisms that are likely to be introduced during the production process.

In cases where the product may fail Challenge test there is a Risk Assessment procedure, which can be used alongside Microbial Limits testing to demonstrate that a product does not support microbial growth. Risk Assessments are carried out by MSL according to ISO 29621:2011.

Standard Preservative Efficacy Testing Services offered by MSL:

- ISO Preservative Efficacy Test Method ISO 11930:2012
- European Pharmacopeia Preservative Efficacy Test Method 5.1.3
- United States Pharmacopeia Preservative Efficacy Test Method 51
- Japanese Pharmacopeia Preservative Efficacy Test Method 19

Risk assessments offered by MSL:

Third Party Microbiological Risk Assessment ISO29621:2011 Cosmetics Microbiology

Reduced Challenge Testing (PETRA):

MSL are pleased to offer their "reduced" Challenge Test suites. These are condensed versions of the Standard Challenge Tests and can be used to predict the outcome of the full analyses. The length of time the test takes and the cost of the test is significantly reduced.

This is particularly useful when formulating new products as a method of quickly checking how effective the preservatives may be, before committing to the full Challenge Test on the final formulation.

Non-Standard Preservative Efficacy Testing:

MSL can offer a much broader range of Preservative Efficacy Tests to meet customer requirements and satisfy the Regulatory requirements of different international regions, as well as offering bespoke testing to suit customer requirements.

It is "best practice" to carry out Preservative Efficacy Testing against customer specific factory isolates. The standard test methods involve testing efficacy against a standard suite of microorganisms. However, this does not always predict how preservatives respond to microorganisms that are intrinsic in the manufacturing environments. Therefore, MSL offers Preservative Efficacy Testing for factory and other isolates. We can also store your isolates for a small fee.