HYGIENICUM

Member of GBAGROUP

Your Challenges Require Smart Solutions.

GMP-certified microbiological laboratory testing

Hygienicum, Institute and Competence Center for Micro- and Molecular Biology, has a GMP-compliant infrastructure around an isolator for sterile testing.

GMP certification includes testing of sterile, non-sterile and biological (endotoxins) manufacturing activities, as well as the import of medicinal products in the same scope of authorization. The portfolio is complemented by NON-GMP tests for cosmetics (preservation load test, safety assessment and microbiology) as well as medical devices (bioburden test).

HYGIENICUM GmbH, Institute for Food Safety and Hygiene, Robert-Viertl-Strasse 7, 8055 Graz-Strassgang, Austria
Phone: +49 316 69 41 08-0, E-Mail: pharma@hygienicum.at

Overview Portfolio

Sterile Pharmaceutical Testing

We carry out the testing of sterile products according to Pharmacopoeia Method (EP) 2.6.1. in the GMP laboratory in a clean room using an isolator (clean room class A).

Endotoxin Testing

We offer the endotoxin test in method A (Gel Clot Limit Test) according to EP 2.6.14. and in the most modern version by using recombinant factor C (rFC) with a fluorimetric method according to EP 2.6.32.

Testing of non-sterile products for total germ count and specific germs

The determination of the total bacterial count (TAMC and TYMC) and testing for specified germs are carried out for pharmaceutical customers according to EP 2.6.12. and 2.6.13. For the testing of cosmetic products, relevant ISO methods are used.

Bioburden analytics

In addition, there are other in-house methods for determining the bioburden.

Germ / mould identification

Furthermore, we can also offer you germ identification by means of biochemical confirmation or on a DNA basis by sequencing.

Microbiological environmental monitoring

To check and assess the hygienic, aseptic condition of your clean rooms or hygienic areas, we offer the evaluation of your monitoring samples (plates, swabs, etc.).

Preservation loading test

The preservation of pharmaceutical or cosmetic products is an important component of product quality. We "challenge" the microbiological quality over a longer period of time and thus check your product for sufficient preservation according to ISO 11930 and thus make an important contribution to product safety.

Validation / Qualification

Validation and qualification are top priorities in the GMP area. We offer these for sterile and non-sterile products. Clean rooms including isolators, autoclaves and incubators are regularly qualified. For this purpose, we carry out population determinations of bioindicators (spore strips, platelets, etc.) with professional incubation at the correct temperature and over defined periods of time.

TOC analytics

The determination of total organic carbon (TOC) is an indirect measure of organic substances. This determination can also be used to monitor the performance of various operations, e.g. in the production of pharmaceuticals or medical devices.