Medistri.SA

Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

www.medistri.swiss

Laboratory Analyses for Pharmaceutical Vials - Medistri

🚀 **Laboratory Analyses for Pharmaceutical Vials**

Medistri's expansion has always been focused on helping the world's most innovative healthcare companies to get their products on the market in the safest & fastest approach.

Specifically, by listening to our pharmaceutical & biotechnology customers, we've engineered our company's infrastructures to be working hand in hand with our quality team, under one roof, at all times.

On a daily basis, our pharmaceutical customers benefit from our range of Tests for Pharmaceutical Vials

✅ Bacterial Endotoxin Testing:
Following USP/EP guidelines as part of our pharmaceutical testing. These tests, which use limulus amebocyte lysate (LAL) reacts with minute levels of endotoxin, providing definitive proof that endotoxins are not present in the manufacturing process. Medistri’s Laboratory performs bacterial endotoxins in samples throughout the manufacturing process; from raw materials, pharmaceutical water, in-process intermediates, bulk lot release, and final product release.

✅ Sterility Testing:
Medistri provides Sterility Testing of pharmaceutical products, biotechnology products, medical devices and consumer products. Sterility testing is required during the sterilisation validation process as well as for routine release testing.

✅ Sub-visible Particle Testing:
According to USP <788> Injections, the Light Obscuration Method and the Microscopic Method are the preferred approaches to analyze particulate matter. Sub-Visible Particle Testing Through Light Obscuration Method: This method analyses the device rinse solution or injectable product using a light obscuration particulate analyser. Sub-Visible Particle Testing Through Microscopic Method: This method filters the device rinse solution or injectable product through a 0.8 µm grey gridded filter. The filter is then counted microscopically at 100x to determine the number of particles, counting particles in the entire test solution.

✅ EO Residual Testing:
Ethylene Oxide (EO) Residuals Analysis is used to identify and quantify the residual levels of ethylene oxide, ethylene chlorohydrin, and ethylene glycol by gas chromatography. When products have been sterilized through Medistri’s EO Sterilization Infrastructure, Medistri’s laboratory tests to demonstrate the safety of products sterilized by EO by determining compliance with accepted residual limits.

✅ Bioburden Testing:
For single-use products are terminally sterilised using EO, Steam or radiation technologies. Manufacturers are required to validate the sterilisation process and these validations typically require both bioburden and sterility testing.

✅ Cytotoxicity Testing:
Cytotoxicity testing is used to determine the toxicity of medical devices and materials. The test is carried out on all products that come into touch with patients, as well as raw materials and devices that will be undertaking cleaning validation. Cytotoxicity testing evaluates whether a material can affect living cells and demonstrate that their products are not cytotoxic.

👉 Medistri's In-House laboratory will perform your Bacterial Endotoxin Testing, Sterility Testing, Sub-Visible Particle Testing, EO Residual Testing, Bioburden Testing, Cytotoxicity in our GMP Accredited laboratory in Switzerland (also certified with ISO 17025) to analyse and demonstrate the safety of your sterile medical device.Our laboratory is host to state-of-the art equipments - you can come visit our facilities by contacting us on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

To learn more about our services visit on our website at www.medistri.swiss or directly contact our team at contact@medistri.swiss.

- The Medistri team

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#Pharmaceutical #MedicalDevices #MedTech #BioTechnology
#SterilizationServices #Laboratory Services

Medistri’s Contract EO Sterilisation Services :
https://www.medistri.swiss/service/our-laboratory