

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

www.medistri.com



Sterilisation for Pharmaceutical Vials - Medistri

Sterilisation for Pharmaceutical Vials

400'000'000 is the number of pharmaceutical vials that Medistri sterilises every year. And we're working towards helping our customers scale even faster.

A pharmaceutical vial is a small container, typically made of glass or plastic, used to store and protect liquid, powder, or lyophilized (freeze-dried) pharmaceutical substances. These vials must be sterilized and sealed with a rubber stopper or a screw-on cap, often secured by a metal crimp or seal. They are commonly used for injectable medications, vaccines, or other substances requiring precise dosing. Vials ensure the contents are protected from contamination and maintain sterility until use.

Sterilizing a pharmaceutical vial is crucial to ensure the safety, quality, and efficacy of the medication it contains. Without sterilization, harmful microorganisms could contaminate the vial, posing serious risks to patient health, such as infections or adverse reactions. Contamination can also compromise the integrity of the drug, reducing its effectiveness or causing unintended chemical changes. Sterilization safeguards the product throughout its shelf life, maintaining its purity and sterility, which is essential for compliance with regulatory standards and for protecting patient safety during administration.

The sterilisation of glass pharmaceutical vials should be performed with a highly specific and welldesigned cycle designed after studying all the critical parameters and their interconnections. The sterilisation parameters used during this process depends primarily on the nature and design of the containers, closures and packaging material. A crucial prerequisite of terminal sterilisation is to improve the aseptic manufacturing sterility assurance standard of pharmaceuticals without impacting pharmaceutical validity. Sterilisation methods must deliver a Sterility Assurance Level of 10-6 without influencing the pharmaceutical validity.

Once your products have been sterilised, Medistri will perform your Bioburden Testing, Bacterial Endotoxin (BET), Biological Indicators (BI) Sterility and Ethylene Oxide (EO) residual analysis in our GMP Accredited laboratory in Switzerland (also certified with ISO 17025) to analyse and demonstrate the safety of your sterile medical device.

Medistri is certified GMP compliant by Swissmedic.

- Sterilisation of pre-filled syringes, vials or cartridges.
- Sterilisation of ready-to-fill syringes, vials or cartridges.
- Terminal sterilisation of sealed devices combining a device and drugs (filled syringes, impregnated stents).
- Sterilisation of active ingredients in bulk.

Medistri is a global leader in industrial pharmaceutical vial sterilisation. Our infrastructure allows you to sterilise your pharmaceutical vials at industrial scale 24/7 while ensuring the integrity and durability of your products. Medistri is certified GMP compliant by Swissmedic.

To learn more about Medistri's Sterilisation for Pharmaceutical Vials, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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