# Medistri

Providing Sterilisation & Laboratory Services for the world's most innovative healthcare companies.

## From the Blog

### **Sterilisation for Pharmaceuticals**

March 17th 2025

Sterilization is a critical process for ensuring the safety and efficacy of pharmaceutical products, particularly in packaging and injectable solutions. Medistri offers contract sterilisation services that meet rigorous pharmaceutical manufacturing standards.

Why the pharmaceutical industry chooses Sterilisation with Medistri To sterilize products after manufacturing, Medistri achieves a Sterility Assurance Level (SAL) of 10<sup>-6</sup>—with method especially suited for items that cannot withstand high heat or moisture, such as primary Type 1 glass packaging (syringes, cartridges, and vials).

#### How Medistri's Contract Sterilisation Services work:

Sterilizing pharmaceutical products involves a controlled process that meets the GMP and ISO 11135 standards. Medistri provides in house Sterilisation Validation and Routine Contract Services.

- Sterilisation Validation: In-house validation is performed by our laboratory and quality team at the Domdidier site in Switzerland.
- Sterilisation: Products are loaded into the sterilisation chambers and processed according to a specific Sterilisation Validation Report. The technology penetrates the packaging, sterilizing the product without further handling.
- Degassing: Following sterilization, products are transferred to a degassing chamber to remove residuals.
- Laboratory Testing: Laboratory tests including Bacterial Endotoxin Testing (LAL), Bioburden, incubation of biological indicators, Sterility testing, and Residual analysis are conducted to ensure compliance by our laboratory.



#### **How Medistri Meets your Supply Chain**

Medistri operates two dedicated sites:

- Hungary Site: Operational since 2025 with 1 Chamber.
- **Switzerland Site:** Operational since 2006 with 6 Chambers and housing the team performing the sterilisation validation.

Both sites operate 24/7 and feature sterilisation chambers with a capacity of 16 pallets per chamber with a maximum pallet height of 2.4m. Additionally, Medistri provides full logistical support throughout the process to ensure smooth operations and timely delivery.

Learn more about our Sterilisation services. To ensure the integrity and compliance of your pharmaceutical products, visit our website  $\underline{\text{here}}$  or contact our dedicated team at  $\underline{\text{contact}}$   $\underline{\text{medistri.com}}$ .

— The Medistri Team

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