

FCTS – Sterility test isolator

Applications:

Bio-pharmaceutical

Loads:



Processes:

Bio-decontamination

Sterility testing



The FCTS Sterility Test Isolator has been designed for pharmaceutical samples taken from manufactured drug batches and meets all the requirements of the FDA, EMA, WHO and associated pharmacopoeia as well as all applicable EN standards and directives and international norms.

Powered by

Thema4

Suitable for:

- Injectable liquids
- Ophthalmic ointments
- Sterile antibiotic powders
- Incoming raw materials
- Freeze-dried drugs

Key benefits

Feedback control for superior process repeatability even if load pattern changes

100% air tightness: silicon inflatable patented gasket on all doors

Significantly reduced operational costs: non-proprietary consumables

Thema4: easy integration with other Fedegari machines and SCADA systems

Reliability: Leak testing totally managed by Thema4

Cost-effectiveness: Drastically reduced validation time for cycle and load

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When Fedegari started designing its first isolator, the goal was assuring customers the highest process reliability and repeatability possible.

FCTS sterility test isolator is equipped with the same solution that Fedegari has standardized in bio-decontamination pass-boxes, because the performances and the reliability of third party H₂O₂ vaporizers were not satisfactory. Moreover, with the FHPV there is no need of proprietary consumables, reducing significantly operational costs.

This innovative design provides real time biocide concentration control (over traditional estimated calculations) and is totally managed by Thema4, assuring process reliability.

Through the H₂O₂ sensors and other devices, Thema4 assures that vapor concentration remains extremely constant (within ± 15 ppm) thus making process repeatability the logical consequence. The FCTS sterility test isolator is compliant with the most stringent cGMP guidelines of Pharmacopeia. It has been classified as ISO 5 FDA and Class A EU GMP.

Design and technical features

- Working chamber has non-directional BA surface finishing ($Ra \leq 0.4 \mu m$).
- Air-tightness is 100% guaranteed by ultra-safe doors.
- Equipped with an internal stainless steel trolley for material transfer from pass-box to working chamber assuring continuous loading of the isolator with materials.
- Customizable internal storage and racks: can be designed according to customers' needs.
- Integrated pressure decay leak test both for chambers and gauntlets
- FCTS is modular: customers can choose the positioning of the pass-box, the number of working chambers and gloves.

