



Dispensing Isolator for Sterile HPAPI

Single chamber barrier isolator configured in order to grant the dispensing procedure for API product achieving the following tasks:

- Assure a sterile environment inside the isolator.
- Assure operator protection, when the processed products are highly active

The barrier isolator operates under a positive pressure regime, as required for sterile manufacturing processes.

Connection on the bottom part of the working chamber in interface with the reactor loading device with PTFE gasket in order to allow the operation with high temperature.

Double RTP transfer system on the right side of the isolator.

Oval glove ports with safety bar to prevent the operator access in the working chamber if the temperature at the discharging connection does not correspond to the prefixed acceptable safety range.

Cleaning of the isolator is performed by means of spray ball and washing gun. Integrated weighting scale with 0,02g accuracy. Integrated video camera for visual control of the loading operation.

Integrated H₂O₂ generator for the bio-decontamination of clean, hard, dry surfaces within sealed enclosures for volumes up to 2m³.

TECHNICAL DATA

Dimensions

According to process requirements

Material

Shell: 316L - Structure: AISI304

Gaskets

EPDM / Silicone

Gloves

CSM / EDPM

Surface roughness

< 0,40 µm – contact parts

< 0,80 µm – non contact parts

Filtration

HEPA filters class H14

Cleaning

Spray ball and washing gun

Lighting

Dedicated lamp with min. 500 Lux

Containment level

OEL (8hTWA): <1µg/m³

Control system

PLC system Siemens S7-1200

Headquarters

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Production and Test Facilities

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