

# Teclen® Lyoprotect® Stainless Steel Tray for Lyophilization

## Concept

Teclen® Lyoprotect® Stainless Steel Trays for multiple use are designed for freeze-drying of pharmaceutical APIs (Active Pharmaceutical Ingredients). Thanks to the polished surface, cleaning is easy. The serial number engraved on the tray facilitates the documentation e.g. of the filled-in substances.

All components, including the Lyoprotect® Membrane, can be sterilized in an autoclave. APIs can be produced aseptically in compliance with GMP.

## Membrane

The membrane is designed for single use and can be easily replaced before every new drying cycle. During sublimation, the vapor can escape smoothly via the hydrophobic membrane which protects the API against contamination and also protects the working environment and staff against fly-out.

## Process development

The dimensions of the Stainless Steel Trays permit individual upscaling. In combination with the Stainless Steel Cups\* this allows for a continuous process development from a few milliliters in the laboratory up to a filling volume of 6 liters on a GMP production level. Especially in the last expansion stage, it is



economically viable to make optimum use of the existing shelves by adjusting the dimensions of tray and membrane accordingly.

## Sustainability

The combination of single-use and multiple-use components helps to reduce waste. The high-grade stainless steel tray is very resistant, only the membrane must be discarded.

\* Please see the “Teclen® Lyoprotect® Stainless Steel Cup with Screw-on Ring Cover for Lyophilization” data sheet for further details about Teclen® Cups.

## Product Claims of Teclen® Lyoprotect

- Bacteria-proof container with vapor-permeable membrane
- 100% visual inspection of membrane and components
- Serial number and work's test certificate 3.1 for stainless steel plates
- Components comply with the regulations for materials and articles intended to come into contact with food according to (EC) No 1935/2004 and (EU) No 10/2011
- The Lyoprotect® Membrane does not contain any material of animal origin

# Design Features and Materials

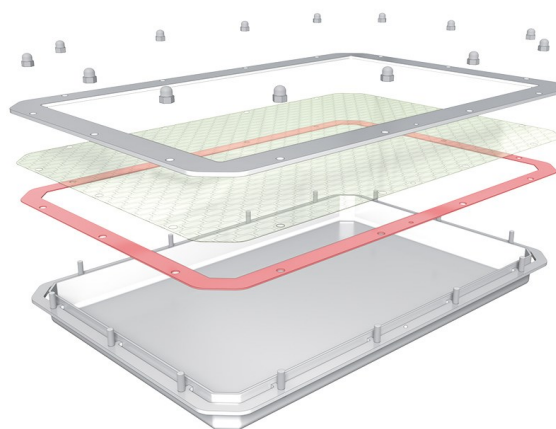
## Multiple-use Components

### Tray with Fixing Frame:

- Stainless steel ANSI 316 L (1.4404) with polished surface ( $R_a < 0.4 \mu\text{m}$ )
- work's test certificate 3.1 for steel plates used
- engraved serial number
- plate thickness: fixing frame 3 mm, tray 2 mm

### Sealing:

- Expanded PTFE flat gasket, 1 mm thick



Teclen® Lyoprotect® Stainless Steel Tray with fixing frame, flat gasket and single-use membrane

## Single-use Component

### Teclen® Lyoprotect® Membrane:

- Expanded PTFE on polypropylene non-woven backing material
- membrane facing the pharmaceutical product after assembly
- asymmetrical design serving as positioning aid



Laser-welded 45° corners facilitate residue-free cleaning

» Please see the Teclen® Lyoprotect® Product Catalog for detailed order information.

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