

## Case Study

### Teclen® Lyoprotect® Tray Tested at Lactosan GmbH & Co KG – Microbial Barrier Performance and Drying Parameters



#### About Lactosan GmbH & Co KG

Starting out as a regional company, Lactosan has become a globally active specialist in the production of lactic acid bacteria.

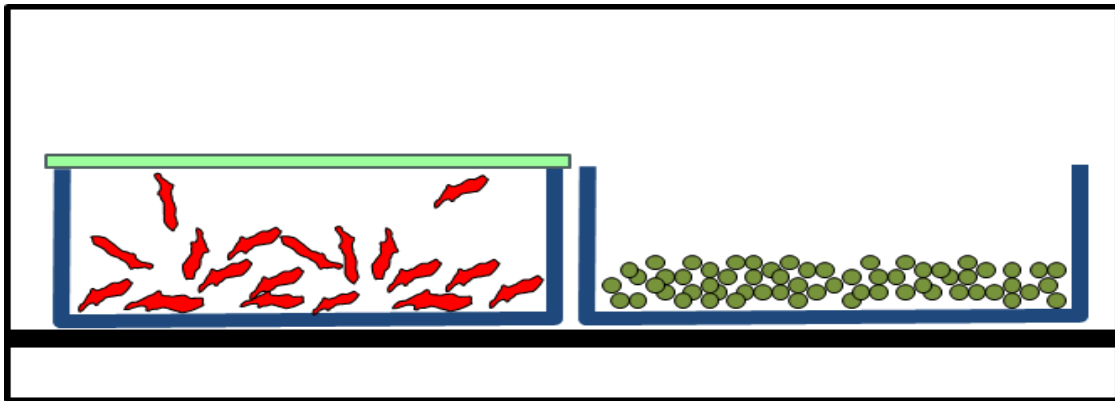
In addition to special products on the basis of living lactic bacteria, Lactosan also produces probiotics for farm animals, strains for human probiotics as well as starter cultures for food. The services offered also comprise contract manufacturing of more than 40 different enzymes for the food or pharmaceutical industry.

With the R&D laboratory and pilot plant, research projects and process developments can be realized in a target-oriented way. The pilot plant permits the production of smaller quantities up to a scale of 300 l for testing purposes.

#### Initial Situation

Mr Mag. Bernhard Hofbauer, working at the R&D department of Lactosan, verified the suitability of the Lyoprotect® Tray for contamination-free freeze-drying of bacteria strains in the course of an internal qualification process. This way, Lactosan would be able to lyophilize different products in one drying cycle in the future. In the event of success, this could save time and money.

During this test, the drying parameters and subsequently the drying results were scrupulously examined in the pilot laboratory. Needless to say that special attention was paid to possible cross-contamination. The aim was to provide evidence that by using the Lyoprotect® Tray, different bacteria strains can be freeze-dried side by side without contaminating each other.



### Test Setup

The picture above demonstrates the setup of the test, which was carried out by Mr Hofbauer in the pilot laboratory:

The Lyoprotect® Tray on the left contained bacterial strains of the type *Lactobazillus plantarum*. These strains were freeze-dried under aseptic conditions and were then examined for the most common pathogenic bacteria as well as for cross-contamination.

The right tray remained uncovered for comparison purposes. It contained bacteria strains of the type *Enterococcus faecium*. By means of agar plates, which were placed in the freeze-drier, fly-out during freeze-drying and contamination of the environment was verified.

### Testing

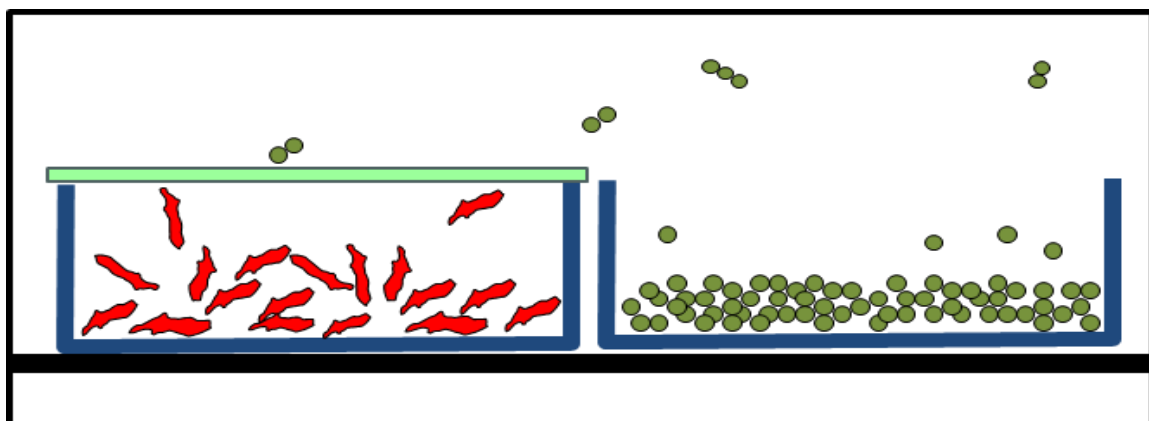
The components of the Lyoprotect® Tray comprise an aluminum tray with accurately fitting fixing frame, a vapor-permeable membrane and a silicone flat gasket.

The tray was assembled under a laminar flow and subsequently filled with the *Lactobazillus plantarum* suspension.

Then, the Lyoprotect® Membrane was positioned and secured with the fixing frame. As next step, the Lyoprotect® Tray and the open tray were placed side by side in the freeze-drier. Both were freeze-dried with the parameters which had been determined for the open tray in the past. After completion of the drying process, the chamber was ventilated. The bacteria strain freeze-dried in the Lyoprotect® Tray was then examined for common pathogenic germs and cross-contamination.

### Test Evaluation

Survival rate after freeze-drying of *Lactobazillus plantarum* in the Lyoprotect® Tray was 80%. Microbiological testing with selective culture mediums showed that the product was free from cross-contamination by *Enterococcus faecium*. Pathogenic germs were not detected, either.



## Conclusion

The behavior of the closed Lyoprotect® Tray is identical to that of an open tray with regard to freeze-drying of bacterial suspensions. No differences were found with respect to powder, survival rate and speed.

Mr Hofbauer concluded that contamination-free lyophilization products can be obtained by using the Lyoprotect® Tray.



Fig.: Lyophilization cake in the Lyoprotect® Tray

*"With Lyoprotect® we can now freeze-dry different formulations together in the same cycle. This saves a considerable amount of time when developing product variants for our customers."*

## Teclen GmbH

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## **About Teclen**

Teclen GmbH is a start-up company founded in January 2017. Teclen develops, produces and sells products for pharmaceutical freeze-drying. The Lyoprotect® products offer solutions for problems such as fly-out and cross-contamination. What is more, an elaborate cleaning validation of the freeze-drier is no longer necessary. Core of the Lyoprotect® products is the vapour-permeable but bacteria-retentive membrane. Various systems for different lyophilization requirements in vials, trays and bulk are available.

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