

## Case Study

### Project Pharmaceuticals uses Teclen Lyoprotect® Bags for lyophilization of innovative cytotoxic drugs



#### About Project Pharmaceuticals GmbH

Project Pharmaceuticals GmbH (PJP) offers optimized formulation and process development for pioneering drug products to the international pharmaceutical and biotech industry.

PJP was founded in 2010 and is located in Martinsried / Munich. The company has become the leading European service provider for the pharmaceutical development of cancer drugs, especially of so-called Antibody Drug Conjugates (ADCs). With these innovative agents, a highly cytotoxic agent is linked to a monoclonal antibody, which is to direct the active substance to the cancer cells in a targeted manner. For this type of drugs, PJP does not only develop

formulations but also efficient and robust manufacturing processes, which are scaled up from in-house pilot installations to industrial sterile manufacturing. In the process, PJP pursues a consequent “Quality by Design” approach, so that the drugs can be processed smoothly and in consistent high quality in the production plant.

The PJP team approached Teclen GmbH, who offers different products for contamination-free lyophilization, with this problem.

### Initial situation

Freeze-drying is an essential step in the development and manufacturing of many drugs in order to increase the stability of active ingredients and to get a storable finished drug product. Especially cancer drugs with highly sensitive active ingredients often imperatively require freeze-drying to avoid degradation and reduction of the effectiveness during storage. So far, the products have been freeze-dried in open glass vials. In this process, the contamination of the freeze-drier by potential fly-out of toxic material from the vial or by glass breakage poses a risk for the staff, and the higher cleaning effort and frequent change of the vacuum pump oil leads to a considerable increase of production costs. Trials to seal the lyophilizate in sterilization bags and to perform lyophilization from within such more or less gas-permeable bags were not successful. The considerable obstruction of the sublimate downflow at the bag's membrane leads to massive changes in the process quality – efficient lyophilization is no longer guaranteed.

### The solution: Lyoprotect® Bag

When Dr. Andreas Schütz of PJP explained their present approach to Rolf Lenhardt of Teclen GmbH, a joint solution was found within no time:

The freeze-drying process was to be identical to the lyophilization process in an open vial to the extent possible. At the same time, it was to ensure total protection of the product and the environment. The specific Lyoprotect® Bag offers this advantage:

The entire assembly (usually a metal tray) of the vials can be inserted into the bag, the open side is closed with a special clip system.

Subsequently, lyophilization of the vials is possible with exactly the same drying parameters used for lyophilization with open containers. It has been demonstrated that there is no obstruction of the sublimate downflow.

Depending on the requirements, the bag can be sterilized in an autoclave before it is filled.



### For vials and bulk

The Lyoprotect® Bag is characterized by an excellent vapor permeability; at the same time it reliably prevents bacteria, germs or particles from passing through the membrane.

As the Lyoprotect® Bag is very flexible, the vials can also be closed directly in the bag with the lyo-plugs by lowering the shelves, thus securely closing the vials.

Thorough tests performed by PJP confirm the excellent suitability of the Lyoprotect® Bag for lyophilization. By means of extensive test series, it was possible to verify the particle tightness of the bags even under extreme conditions. The drying process of sample vials within the Lyoprotect® Bag was completely equivalent to the drying process with open vials. PJP now uses Lyoprotect® Bags for all projects with toxic ingredients and for all batches for the production of sterile preclinical samples.



*“We’d already tried out several sterilization bags, but always had to compromise on the drying parameters. With Lyoprotect® our drying philosophy of the Single-Step-Cycle can now be realized much better – we also consider the Lyoprotect system fit for GMP production of lyophilized drugs.”*

### 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.

#### Teclen GmbH

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