

Case Study

Cilian Uses the Lyoprotect® Bag Direct Fill to Protect their Staff from Enzymes Causing Respiratory Irritation



About Cilian AG

Cilian AG is an innovative biotechnology enterprise, which uses the unique abilities of Ciliates for the industrial production of therapeutically effective recombinant proteins. The company is working on the production of vaccines, monoclonal antibodies as well as on oral preparation for the substitution therapy of pancreatic insufficiency.

By using a new class of production organism (Ciliates) Cilian AG can create a substantially safer, more efficient and more cost-effective production process as this is currently possible for comparable proteins with mammalian cells. Moreover, it is expected that monoclonal antibodies are significantly more effective. Cilian AG is offering this unique technology as CIPEX-System to pharma and biotech companies.

Initial Situation

In their planned production process Cilian AG uses enzymes which can cause irritations of the respiratory system. For this reason, protection of the staff is of the highest priority when freeze-drying these active ingredients.

The product is to be placed in liquid state into a container for lyophilization. Afterwards, it is to be transferred in dried state to a processing co-operation partner. The pack size should be as small as possible for temporary storage before processing. Since a reusable container for freeze-drying would entail an elaborate cleaning process, a single-use solution is more suitable in the current development phase.

The Solution: Lyoprotect® Bag Direct Fill

When Dr. Ingo Aldag, project manager at Cilian, had explained the performance requirements in a meeting with Teclen, different options were discussed.

It became apparent that the most suitable solution would be a small bag which would fit into a laboratory freeze-drier and could directly be filled with the product and then securely be closed. Once closed, the bag can be handled safely and without effort, and the staff doesn't come into contact with the enzymes. The small size and flexible form of the bag allows for a space-saving storage of the dried product. The dried enzyme remains in the Lyoprotect® Bag and is additionally sealed in another light-proof and gas-tight storage bag.

In order to take out the product for processing, the outside bag is opened and the Lyoprotect® Bag is emptied or extracted under a laminar flow cabinet.



“Especially in the DSP development phase, the flexibility regarding bag sizes as well as the rapid availability were decisive factors in favor of the Lyoprotect® Bag. Since open handling with enzyme dusts were viewed as critical, the Lyoprotect® Bags were the ideal solution. For meanwhile two years, we have routinely employed these bags for the lyophilization of enzyme test batches and in process optimization.”

About Teclen

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 vapor-permeable but bacteria-retentive membrane. Various systems for different lyophilization requirements in vials, trays and bulk are available.

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