Case Study

Heraeus Relies on Teclen® Lyoprotect® for the Process Development and Manufacturing of Toxic Substances

Heraeus laboratory for process development, courtesy of Heraeus Deutschland GmbH & Co. KG

The Heraeus Pharmaceutical Ingredients Business Line

Within the globally active Global Business Unit Heraeus Precious Metals, the Business Line (BL) Pharmaceutical Ingredients has specialized in the process development and production of highly potent active pharmaceutical ingredients (hAPIs). This ranges from the synthesis of cytotoxic compounds to registration and market launch. All hAPIs for cancer treatment are fully developed and manufactured at the company's headquarters in Hanau, Germany.

Pharmaceutical Ingredients has been US FDA-approved for more than 25 years and in 2018 once again received an award for the high quality and safety standards applied to the production of their hAPIs.

Initial Situation

The R&D team of BL Pharmaceutical Ingredients is a CDMO (Contract Development and Manufacturing Organization). It develops custom-order chemical synthesis and purification processes, where the staff members research and work with platinum-based and organic active ingredients for chemotherapy. Hence, a reliable protection is indispensable for the staff members as well as the environment. Furthermore, the active ingredients must be protected from contamination or cross-contamination.

Heraeus manufactures active pharmaceutical ingredients in compliance with GMP. Often only a few grams up to 100 grams of these highly toxic APIs are required per batch. This relatively small amount is a particular challenge for the lyophilization of active ingredients, as a laboratory or pilot freeze-drier is frequently not located inside an isolator or does not have the necessary CIP/SIP equipment. Due to capacity utilization or cross-contamination risks, switching to a suitable production facility is difficult or not possible at all

The Solution: Lyoprotect® Cup

Under discussion between the R&D team of Pharmaceutical Ingredients, the responsible QA representative, and staff members of Teclen GmbH, it soon became obvious that the Lyoprotect® Cup would be a good solution in order to avoid contamination risks. However, the cup still had to be customized.

The team selected the high-grade, resistant stainless steel 1.4404 (ANSI 316L) as material. By polishing, a mean roughness of Ra ≤ 0.4 µm is obtained and the cup can be even more easily cleaned without leaving any residues.
The QA representative liked details such as the radius between bottom and sides as well as a consecutive serial number.

Lyoprotect® Cup with consecutive serial number

The Lyoprotect® expanded PTFE membrane ensures that no contaminants can enter from the outside and that toxic dusts remain inside the container. Due to the very porous structure of the membrane, water vapor can escape easily during freeze drying. Freeze-drying parameters determined on an open container can be transferred to the Lyoprotect® Cup with Membrane without limitation. The same filling level must be applied.

The screw-on ring cover and a silicone O-ring with FEP sheathing ensure tightness of the cup system. The FEP O-ring is resistant against acids, caustic soda and solvents.

The R&D team of BL Pharmaceutical Ingredients agrees:

"We have expanded our performance spectrum and can now lyophilize highly toxic custom-order APIs in our laboratory in Hanau, Germany, in compliance with GMP. The Lyoprotect® Cup with Membrane is a principal item of the freeze-drying process."

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; a 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 or trays are available.

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