



Lyophilization

New Capacities at Fresenius Kabi Austria - Plant Graz

Lyophilization of aqueous solutions and liposomal formulations is a common technology applied for compounds that cannot attain an adequate shelf life in aqueous solution because they are susceptible to hydrolysis, unwanted reactions with other substances or loss of activity for other reasons.

At Fresenius Kabi lyophilization has been a well-established technology for some time. Recently, a new small volume parenteral (SVP) filling line with an integrated freeze dryer has been installed at the Graz plant to add capacity for third-party manufacturing. Fresenius Kabi Product Partnering can now offer services in the development and commercial manufacturing of lyophilized products for aqueous and liposomal formulations.

Development of Formulation and Lyophilization Cycle - I&D Graz ● ● ● ●

- Formulation development
- Initial analysis using cryo-microscopy to find the collapse temperature
- Development of lyophilization cycle in a small-scale freeze dryer (shelf area: Approx. 0.1 m²) with temperature sensors in vials
- Scaling-up of the lyophilization cycle to a pilot-scale freeze dryer (shelf area: Approx. 1.0 m²)
- Evaluation of the formulation and lyophilization cycle based on the shape of the product cake, reconstitution time and analytical endpoints



Commercial manufacture of lyophilized product - Plant Graz ● ● ● ●

- State-of-the-art aseptic filling line and lyophilization unit, freeze dryers are fully integrated into the aseptic filling line.
- Can work with high-potency and biological APIs
- Able to compound and fill cooled bulk solution
- High-speed SVP line with different dosing systems
- Isolator system
- In-line control of filling volume
- Vials size: 2-30 mL
- Fully-automated transfer of vials from the filling line to the freeze dryer
- Shelf area: Currently 19 m² but with extendable lyophilization capacities

