Recent Trends in Lyophilized Delivery Devices and Packaging

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Packaging systems for lyophilized products typically consist of a glass vial and an elastomeric closure as primary packaging components, and an aluminum/plastic flip cap as secondary packaging component. Alternatively, the lyophilization can take place in dual-chamber cartridges where the freeze-dried product is available in one chamber of the cartridge and the diluent in the second chamber.

The first part in this chapter discusses advances in the area of these packaging components and systems.

Elastomeric Closures

Closure Geometry

Lyophilization closures have to be compatible with the freeze-drying process. The first step in the process is the filling of vials with drug solution, followed by partial stoppering of the vials, meaning that the lyophilization closures are only partially inserted in the vial neck (Fig. 1). A major part of the stopper plug is still protruding above the vial neck opening. The partially stoppered vials are then transported into a freeze-drying chamber. There, the aqueous drug solution is first frozen and then the water is removed from the frozen state by sublimation at low temperature and pressure (primary drying). After that the temperature of the vials is increased, leading to the removal of the last parts of water at low pressure and increased temperature, higher than but still fairly close to what is commonly called "room temperature" (secondary drying). Only thereafter, the vials are fully stoppered by the action of

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