FRESENIUS KABI

Product Partnering

Fact Sheet (12)

Aseptic filling of bags

Bags are the primary container of choice for parenteral nutrition, as well as for the isotonic buffered infusion solutions that are often used along with injectable drugs. In contrast to glass bottles, bags are more convenient and safer for healthcare professionals and avoid product contact with rubber stopper materials. Most products sold in bags are terminally sterilized due to their nature and composition. However, terminal sterilisation of bags is not compatible with heat-sensitive compounds. Therefore, demand for products in aseptic bags is increasing steadily.

Aseptic manufacturing processes put high demands on the manufacturing plants. Personnel and equipment must comply with stringent guidelines. High standards for engineering, training, monitoring and house-keeping have to be in place at the plant, in order to guarantee stable good performance of aseptic processes.

Fresenius Kabi Product Partnering offers the aseptic competence of Fresenius Kabi plants to its customers.

Selection of Bags for Aseptic Processing

- Pre-printed bags are pre-sterilized before delivery and supplied in overpouches
- Currently, PVC containing bags are used for the aseptic filling process
- Development and implementation of new bag formats and bag materials on demand

Aseptic Filling Line

- Dedicated filling line for aseptic filling of bags
- Inline automated CIP/SIP procedure
- 2-isolator concept (separation isolator and filling isolator)
- Loading and unloading of isolators via mouse holes protected by LAFs
- Filling via filling port
- Welding of the filling port after filling
- Oxygen protection if required (nitrogen gassing, overwrapping, and oxygen scavenger)
- Batch size: Up to several thousand liters
- Extendable capacities available

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