MediZap

Advanced Sterilization

The Best Primary Packaging Solutions for Injectables

Packaging selection is critical when developing compounded sterile parenteral products. The primary packaging system must be compatible with the product formulation, maintain sterility, and be convenient for use by patients or medical administrators.

Packaging selection for parenteral products must also consider the product's intended use. For example, single-dose injectables may require primary packaging with smaller volumes to prevent wastage, while multi-dose products may require larger volume primary packaging to accommodate multiple doses.

In addition to compatibility and convenience, the packaging system must have appropriate seal strength and integrity to protect against microbial contamination. Every compounder is required to have completed container closure testing under USP standards to prove sterile seal performance. This is especially important for sterile drug products, as microbial contamination can compromise the efficacy and safety of the product, leading to potential health risks for patients.

Therefore, it is critical to carefully evaluate the primary packaging options available for parenteral products and select a suitable packaging system for the compounded drug product formulation and intended use while ensuring the integrity of the container-closure interface to maintain sterility throughout the product's shelf-life.

What are the primary packaging systems used for parenteral products, and what are some factors to consider when selecting a packaging system for parenteral products?

There are five primary sterile packaging systems used for parenteral products: vials (glass and plastic), prefilled syringes (glass and plastic), ampoules (glass), cartridges (glass), and bags (plastic).

Factors to consider when selecting a packaging system for parenteral products include the type of product, material compatibility with the product formulation, convenience to the patient or medical administrator, and the integrity of the container-closure interface in maintaining sterility throughout the product's shelf life.

1. **Vials:** A vial can be either glass or plastic with a rubber stopper and cap or seal, that accommodates a syringe with a needle for draw-up. Typically, you can select either amber (for UV protection) or clear across both materials. There are specific vial applications used when selecting to lyophilize liquid into powder. They are the most common form of sterile primary packaging for parenteral products and are suitable for various drug formulations. Furthermore, plastics are more likely to interact with the drug product (absorption, migration, and leaching) unless a glass-lined plastic vial is utilized.

2. **Prefilled Syringes:** Prefilled syringes are titrated with a specific drug formulation volume and designed to be used only once. They are available in glass or plastic with varying needle gages. They offer several advantages over other primary packaging systems, including ease of use, accuracy in dosage, reduced risk of medication errors, and improved patient safety.

3. **Ampoules:** Ampoules are small, single dose glass containers that are sealed by melting the glass at the neck of the container. Since ampoules only use one type of material, there is less potential interaction with the drug product as glass packaging material is used. However, there is potential for glass particles to enter the drug product solution when the ampoule is broken upon opening.

4. **Cartridges:** Cartridges are similar to syringes in that they have a product filled into a glass tube closed on either side by a rubber plunger and a rubber disk seal. Unlike syringes, cartridges are designed to insert into a delivery pen device. Cartridge-pen systems allow for dose accuracy and patient convenience. All cartridge-pen systems use replaceable needles, but only some pens use replaceable cartridges. Cartridges in delivery pens offer repeatable dosing accuracy compared with prefilled syringes designed for single use. Because dosing with a pen involves dialing a mechanical device as opposed to looking at the side of a syringe, cartridge systems increase visual acuity and further assure accurate home dosing.

5. **Bags:** Bags are flexible containers made of plastic used for intravenous (IV) fluid administration. Consideration should be made regarding compounded drug interaction with plastic polymers of IV bags. They are suitable for infusion pumps and offer several advantages, including ease of handling and increased patient comfort.

MediZap's high-end secondary packaging solutions called Steri-Packs are perfectly set up to work with our E-Beam | X-Ray terminal sterilization process and ensure your parenteral drugs are secure throughout transit to and from our contract sterilization facility.