- Description of the physical appearance of the constituted solution
- Directions for proper storage of the constituted solution
- An expiration date limiting the storage period during which the constituted solution may be expected to have the required or labeled potency if stored as directed.

Strength and Total Volume for Single- and Multiple-Dose Injectable Drug Products

The primary and prominent expression on the principal display panel of the label needs to be the strength of the active ingredient per total volume, for example:

- Strength per vial: 500 mg/10 mL (or in units per total volume)
- Strength per mL: 50 mg/mL (or in units per mL)

If the container volume is less than 1 mL, then the strength per fraction of 1 mL should be the expression, for example, 12.5 mg/0.0625 mL

Medication errors cannot completely be eliminated by prominent strength labels as insulin is a primary example. However, meeting this requirement for label strength prominence certainly will help to reduce the potential for medication errors.

Aluminum in LVPs, SVPs, and PBPs Used in TPN Therapy

The aluminum content of large-volume parenterals (LVPs) used in total parenteral nutrition (TPN) therapy must not exceed 25 μg per liter. The package insert (see the "Precautions" section) of LVPs used in TPN therapy must state that the drug product contains no more than 25 μg of aluminum per milliliter. For small-volume parenterals (SVPs) and pharmacy bulk packages (PBPs), the immediate container label used in the preparation of TPN parenterals should state, "Contains no more than 25 μg/L of aluminum." The maximum level of aluminum as expiry must be stated on the immediate container label of all SVPs and PBPs used in preparation of TPN parenterals with the statement "Contains no more than ____ μg/L of aluminum" (the USP leaves this blank, to be filled in by the manufacturer). This maximum amount of aluminum must be stated as the highest of either the highest level for the batches produced during the past three years or the highest level for the latest fiveb batches.

The package insert for any and all products used in the preparation of TPN products must contain a warning statement in the "Warning" section of the labeling with the warning statement being word-for-word what is published in this section of the USP <1> Injections.

Packaging

Containers for Injection

The packaging system must not interact physically or chemically with the product stored within the package. The container must be composed of materials that allow inspection of the contents. Individual monographs will state the type of glass (or plastic) preferable for each parenteral preparation.

Containers are closed or sealed to prevent contamination or loss of contents. Container closure integrity testing must be performed to validate the integrity of the packaging system against any kind of microbial contamination or chemical or physical impurities. The packaging system must be able to protect the product when exposed to anticipated extreme conditions of manufacturing, storage, shipment, and distribution.

Closures for multiple-dose containers must permit the withdrawal of the contents without removal or destruction of the closure. The closure must seal itself after the needle is removed to protect the product against contamination. Validation of multiple-dose container integrity must include verification that such a package prevents microbial contamination or loss of product contents under simulated use conditions of multiple entry and use.

Potassium Chloride for Injection Concentrate and Neuromuscular Blocking and Paralyzing Agents

The USP contains two very specific paragraphs for two kinds of injectable products—potassium chloride for injection concentrate and neuromuscular blocking and paralyzing agents. A black closure system on a vial (black flip-off seal and black ferrule to hold the elastomeric closure)