657—20.9(126,155A) Control of bulk drug substances, components, containers, and closures. Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to ensure that the containers and closures are suitable for their intended use.

20.9(1) *Storage.* Components, bulk drug substances, drug product containers, closures, and bagged or boxed parts of drug product containers and closures used in the compounding of drug products shall be handled and stored in a manner to prevent contamination and to permit inspection and unhindered cleaning of the work area, including floors. Components, bulk drug substances, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first.

20.9(2) *Sterile product containers and closures.* Drug product containers and closures intended for use in the compounding of sterile products shall be handled, sterilized, and stored in compliance with the requirements of 657—Chapter 13. Procedures shall be written, implemented, and followed for cleaning, sterilizing, and processing drug product containers and closures to remove pyrogenic properties.