

WAC 246-878-090 Control of components and drug product containers and closures. (1) Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.

(2) 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. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. 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 assure that they are suitable for their intended use.

(3) Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists, or under the pharmacist's supervision.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-090, filed 4/6/94, effective 5/7/94.]