

WAC 246-895-080 Component and drug product containers and closures. (1) Component and drug product containers and closures shall:

(a) Not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quantity, or purity of the product or its components beyond the official or established requirements;

(b) Provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product; and

(c) Be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Containers and their components for parenterals shall be cleansed with water which has been filtered through a nonfiber-releasing filter.

(2) Standards or specifications, methods of testing, and, where indicated, processing to remove pyrogenic properties shall be written and followed for component and drug product containers and closures.

(3) Except as provided for in WAC 246-895-090, drug product containers and closures shall not be reused for component or drug product packaging.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-895-080, filed 5/28/92, effective 6/28/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), re-codified as § 246-895-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11). WSR 88-01-025 (Order 208), § 360-46-081, filed 12/9/87.]