WAC 246-895-070 Components. All components and other materials used in the manufacture, processing, and packaging of drug products, and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary, and orderly manner. Adequate measures shall be taken to prevent mixups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a quality control unit. Control of components shall include the following:

(1) Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.

(2) An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one or more tests to establish the specific identity.

(3) Sample containers shall be identified so that the following information can be determined: Name of the material sampled, the lot number, the container from which the sample was taken, and the name of the person who collected the sample.

(4) Containers from which samples have been taken shall be marked to show that samples have been removed from them.

(5) Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

(6) Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate specifications.

(7) Representative samples of components liable to microbiological contamination shall be subjected to microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

(8) Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity at time of use. This requires the following:

(a) Approved components shall be handled and stored to guard against contaminating or being contaminated by other drugs or components.

(b) Approved components shall be rotated in such a manner that the oldest stock is used first.

(c) Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

(9) Appropriate records shall be maintained, including the following:

(a) The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.

(b) Examinations and tests performed and rejected components and their disposition.

(c) An individual inventory and record for each component used in each batch of drug manufactured or processed.

(10) An appropriately identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least two years after distribution of the last drug lot incorporating the component has been

completed or one year after the expiration date of this last drug lot, whichever is longer.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-895-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), § 360-46-070, filed 10/10/88; Order 133, § 360-46-070, filed 8/4/77.]