WAC 246-895-100 Laboratory controls. Laboratory controls shall include the establishment of scientifically sound and appropriate written specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality and purity. Laboratory controls shall include:

(1) The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of drug components, product containers, and their components subject to deterioration.

(2) A reserve sample of all active ingredients as required by WAC 246-895-070.

(3) The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly identified.

(4) The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drug products. Such samples shall be adequately representative and properly identified.

(5) Adequate provisions for checking the identity and strength of drug products for all active ingredients and for assuring:

(a) Sterility of drugs purported to be sterile and freedom from objectionable microorganisms for those drugs which should be so by virtue of their intended use.

(b) The absence of pyrogens for those drugs purporting to be pyrogen-free.

(c) Minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances.

(d) That the drug release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.

(6) Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.

(7) A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least two years after the drug distribution has been completed or one year after the drug's expiration date, whichever is longer.

(8) Provision for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least two years after distribution has been completed or one year after the drug's expiration date, whichever is longer.

(9) Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.

(10) Provision that firms which manufacture nonpenicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such nonpenicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in humans and the product is contaminated with an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

[Statutory Authority: RCW 18.64.005. WSR 92-12-035 (Order 277B), § 246-895-100, 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), recodified as § 246-895-100, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), § 360-46-090, filed 10/10/88; Order 133, § 360-46-090, filed 8/4/77.]