

WAC 246-895-110 Stability. There shall be written procedures for assurance of the stability of finished drug products. This stability shall be:

(1) Determined by reliable, meaningful, and specific test methods.

(2) Determined on products in the same container-closure system in which they are marketed.

(3) Determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling), as well as on the reconstituted product.

(4) Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-895-110, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005. WSR 88-21-025 (Order 220), § 360-46-100, filed 10/10/88; Order 133, § 360-46-100, filed 8/4/77.]