

WAC 246-878-100 Drug compounding controls. (1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.

(2) Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container), the new container shall be identified with the:

- (a) Component name; and
- (b) Weight or measure.

(3) To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

- (a) Capsule weight variation;
- (b) Adequacy of mixing to assure uniformity and homogeneity;
- (c) Clarity, completeness, or pH of solutions.

(4) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

[Statutory Authority: RCW 18.64.005. WSR 94-08-101, § 246-878-100, filed 4/6/94, effective 5/7/94.]