



Quality Assurance in Pharmaceutical Compounding - Weight Assessments

Hard Capsules—

- Zero or tare balance with an empty capsule.
- Accurately weigh each individual filled capsule from a representative sample of the finished batch (for example, a minimum of 5% of total capsules or 10 individual capsules, whichever is less) and record the weight of each finished capsule on the compounding record.
- Calculate the theoretical weight of a finished capsule's contents.
- Compare the actual content weight of each finished capsule in the representative sample with the theoretical weight of a finished capsule's contents.
- Determine if there is a deviation outside $\pm 10\%$ with any weight of a finished capsule's contents and the theoretical weight of a finished capsule, and if so,
 - Review the compounding record to ensure no steps were omitted.
 - Repeat with a larger representative sample of the finished batch (10% of total capsules or 20 individual capsules, whichever is less). Do not mix with the first batch tested.
- If a deviation outside of $\pm 10\%$ is discovered in the second representative sample, then destroy the batch.

Other Solids (Including Tablets, Suppositories, Inserts, and Lozenges)—

- Accurately weigh each individual dosage unit from a representative sample of the finished batch (for example, a minimum of 5% of total tablets or 10 individual tablets, whichever is less) and record the weight of each dosage unit on the compounding record.
- Calculate the theoretical weight of the dosage unit.
- Compare the actual weight of each dosage unit in the representative sample with the theoretical weight of a dosage unit.
- Determine if there is a deviation outside $\pm 10\%$ with any weight of a finished dosage unit and the theoretical weight of a finished dosage unit, and if so,
 - Review the compounding record to ensure no steps were omitted.
 - Repeat with a larger representative sample of the finished batch (10% of total tablets or 20 individual tablets, whichever is less). Do not mix with the first batch tested.
- If a deviation outside of $\pm 10\%$ is discovered in the second representative sample, then destroy the batch.

Semi-Solids (Including Creams, Gels, and Ointments)—

- Accurately weigh an empty container and record the weight on the compounding record.
- Fill an empty container with the final compounded preparation.
- Calculate the theoretical weight of the compounded preparation.
- Weigh the filled container.
- Determine if there is a deviation outside of $\pm 10\%$, and if so, review the compounding record to ensure no steps were omitted. If the deviation cannot be explained, destroy the batch and prepare a new one.

Additional Quality Assurance Checks Before Packaging Semi-Solids—

- Visually inspect the preparation for foreign materials and expected appearance.
- Measure pH, when applicable.

source: USP Chapter <1163>, Current with USP 38-NF 33