spectrum®
PHARMACY PRODUCTS
Distributed by Astral Scientific

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 ±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 ±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 ±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 ±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 ±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

ASTRAL SCIENTIFIC PTY LTD | **ABN:** 82 003 316 603
TOLL FREE: 1800 221 280 | **T:** (02) 9540 2055 | **F:** (02) 9540 2051
W: www.compoundingchemicals.com.au | **E:** sales@compoundingchemicals.com.au
P.O Box 232, Gymea NSW 2227