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PHARMACY PRODUCTS
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Non-sterile Personnel Training & Assessment Guidelines

USP Chapter <795> states that all personnel involved in the compounding, evaluation, packaging, and dispensing of non-sterile preparations shall be properly trained for the types of compounds prepared and it is the responsibility of the compounder to ensure that a training program has been implemented and is ongoing. Compounding personnel should be evaluated at least annually. Steps in the training process should include the following:

- Read and understand USP <795>
- Read and understand pharmacy SOPs
- Train in handling, storage and disposal of hazards
- Document all training – in employee portfolio
- Compounder demonstrates process, guides the employee and employee repeats the process without assistance, but under supervision
- When verbal and functional knowledge of the process is demonstrated employee compounds without assistance, but under supervision
- When the compounder is satisfied with the employee's knowledge and proficiency the compounder will document that the employee was appropriately trained
- The compounder will monitor the employee's work ensuring calculations and work are accurate and adequately performed

Suggested yearly assessment of competency

Document complete mastery, incomplete master or training in progress for the following task – file in employee portfolio:

- Selection of correct active and inactive ingredients
- Accurately records or verifies mfg or distributor, lot number and expiration date of each ingredient
- Compounding workflow prevents medication errors
- Directions on compounding master formula or compounding document are followed
- Chemicals are measured, weighed and mixed in manner to prevent cross contamination (i.e. inside fume hood)
- Tablets and/or crystalline ingredients are thoroughly triturated
- Suspensions, creams and ointments are thoroughly mixed and/or milled
- Capsules are compounding using correct technique with minimal waste or powder loss
- Capsules pass statistical analysis
- All materials are together and presented to pharmacist for final product check/release

Suggested potency validations – per PCAB™ (ACHC) standards

Test potency of the API in one preparation for each compounder every six months for each of the following preparations categories and file in employee portfolio:

- Creams, Gels and Ointments
- Capsules
- Troches, Lozenges, Suppositories and Lollipops
- Solutions and Suspensions

Example of compliance: Two technicians compound preparations from each of the four categories above over the course of a year. The pharmacy is deemed compliant if it has tested two preparations for potency from each category for each technician, a total of 8 tests.

Sources: USP <795>, PCAB™ (ACHC) Standards and Surveys

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