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Quality control of suppositories

QUALITY CONTROL procedures listed in the US Pharmacopeia (USP30-NF25) for manufactured suppositories include identification, assay, and, in some cases, water content, residual solvent, dissolution, and content uniformity:

- **Identification:** Identification tests are commonly used for the identification and confirmation of official articles.
- **Assay:** Assay and test procedures are used to determine compliance with the pharmacopelial standards of identity, strength, quality, and purity. Chromatographic methods are commonly used for detection and quantitation.
- **Dissolution:** Dissolution testing is used to determine compliance with the dissolution requirements, if present in the individual monographs. The test measures the rate and extent of a drug dissolving in a defined medium under defined conditions.
- **Water:** As many pharmacopelial articles either are hydrates or contain water in adsorbed form, the determination of water content may be important in demonstrating compliance with Pharmacopelial standards. Three methods are commonly used: Method I is a titrimetric method, Method II is an azeotropic method, and Method III is a gravimetric method.
- **Content uniformity:** Content uniformity is required in some monographs to ensure the consistency of dosage units. These dosage units should have a drug substance content within a narrow range around the label claim. Weight variation and content uniformity testing involving groups and individual dosage units are used.
- **Residual solvents:** For pharmacopelial purposes, these are defined as organic volatile chemicals that are used or produced in the manufacture of

drug substances or excipients, or in the preparation of drug products. They are not completely removed during processing but should be removed to the extent that is possible and reasonable.

Stability considerations in dispensing practice for suppositories also include observations on excessive softening and oil stains on packaging. Compounded suppositories can be checked for calculations of theoretical and actual weight and weight variation, color, hardness, surface texture, and overall appearance.

Suppository quality control includes physical and chemical aspects of the product (Box 9.1). Physical analysis includes visual examination (physical appearance), uniformity of weight, uniformity of texture, melting point, liquefaction time, melting and solidification time, and mechanical strength. Chemical testing includes analysis of the activity and dissolution testing. The uniformity of texture can be assessed by sectioning a suppository longitudinally and laterally, and ensuring that each section presents a smooth, uniform surface.

A list of official USP suppositories and required quality tests is given in Table 9.1.

Physical analysis

Visual examination

Color and the surface characteristics of the suppository are relatively easy to assess. It is important to check for the absence of fissuring, pitting, fat blooming, exudation, sedimentation, and the migration of the active ingredients. Suppositories can be observed as an intact unit and also by splitting them longitudinally.

Quality Control Of Suppositories Pharmaceutical Press

B Lingard



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