Specifications: How Industry Interpret USP’s Standards in Monograph, and Regulatory Requirements; Purity is NOT microbiology

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“Quality means that the dietary supplement consistently meets the established *specifications* for identity, purity, strength, and composition, and limits on contaminants,…”

- § 111.75(a)(1)(i) Your must conduct at least one appropriate test or examination to verify the identity …

- § 111.75 (h)(1) You must ensure that the tests and …the specifications are .. appropriate, scientifically valid methods.
USP Powdered Ginkgo Extract

- **Identification**: HPTLC and HPLC tests for the ratio and relative abundance of the flavonol glycosides and terpene lactones.
  - Orthogonal tests
  - Multiple tests may be needed (USP General Notices 5.40: When a compendial Identification test is undertaken, all requirements of all specified procedures in the test must be met to satisfy the requirements of the test.)
- ** Constituents**: Contents of flavonol glycosides (22% - 27%); terpene lactones (5.4% - 12.0%); bilobalide (2.6% - 5.8%).
  - Botanical fingerprint
- **Limits for contaminants**: Pesticide residues; elemental impurities; microbial load; Limit of residual solvents.
- **Specific tests**: Limits for rutin and quercetin; Limits for Ginkgolic acid.
Industry Interpretation of USP Monographs

A USP Verification Program Perspective

- Raw Material Specifications
  - Lack of compliance with a USP monograph
    - Basing a specification on the supplier CofA with little or no critical evaluation
  - Insufficient evidence of compliance
    - Supplier may state compliance with USP, or other compendium, but specifications on the CofA do not reflect that

- Use of Analytical Variability / Method Uncertainty at the time of release
  - Analytical variability is built into the acceptance range in the monograph

- Compliance with Upper Acceptance Limits

- Use of Alternative Methods, Lack of Adequate Validation or Verification