

USP Open Forum

Multi-Ingredient Dietary Supplement Products:

Development of Quality Tests

May 6, 2021 • 10:00am–12:00pm ET

Virtual Meeting



Role of USP General Chapters and Compliance

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USP Documentary Standards – Compendial Hierarchy



Monographs

General Chapters

General Notices & Requirements

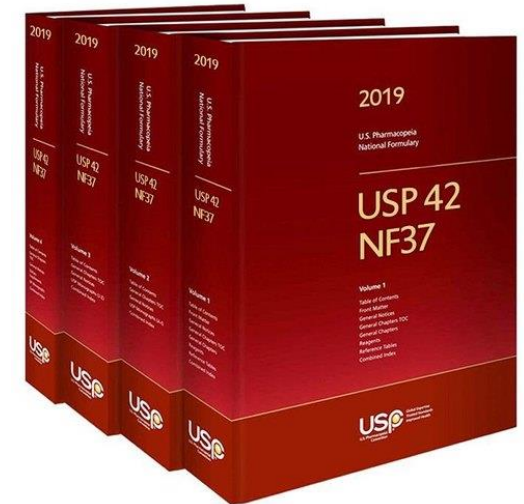
- Presents basic assumptions, definitions and default conditions for interpretation and application of *USP-NF*
- Applies to all articles recognized in *USP-NF* and to all general chapters unless specifically stated otherwise
- Monograph requirements supersede General Notice and General Chapter requirements in case of conflict

- General chapters provide guidelines on activities related to tests and procedures in monographs
- General chapters may contain descriptions of tests and procedures, general information on interpretation of compendial requirements, or general guidance on official substances or official products
 - <1> to <999>: General tests & Assays
 - <1000> to <1999>: General Information, Non-Mandatory
 - \geq <2000>: Dietary Supplements

USP Dietary Supplement Monographs



- For a specific Dietary Ingredient or Dietary Supplement Product
 - A list of official and validated tests
 - Their analytical procedures
 - Their acceptance criteria
 - Together these define specifications for
 - *Identity*
 - *Purity/Limits for Contaminants*
 - *Content (Strength/Composition)*
 - *Quality (Performance and Other Requirements)*



General Chapters – Requirements for Compliance



- ▶ <1> - <999> General Tests and Assays
 - Compliance with chapters is required if chapters are cited in monograph or General Notices and compliance with monograph is required (e.g., for APIs and finished drug products in the U.S.)
- ▶ <1000> - <1999> Informational Chapters
 - Provide information about standards, assays etc.
 - Non-Mandatory
- ▶ Above <2000> Chapters specifically related to dietary supplement ingredients/products
 - Required ONLY if cited in monograph or General Notices when claiming compliance to USP (compliance with residual solvents and elemental contaminants is always required when applicable per GN 5.60.20 if claiming compliance with USP)
- ▶ Dietary Supplement monographs may also cite chapters below <2000>
- ▶ <2800> is intended to provide tools for industry – not mandatory

Stay Connected

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