Vitamins with Minerals Oral Powder
New monograph proposal

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What is in a USP Monograph?

- A list of official and validated tests
- Their analytical procedures
- Acceptance criteria for each test
- Together these define specifications for
  - Identity
  - Purity/Limits for contaminants
  - Content (Strength/Composition)
  - Quality (Performance and other requirements)

- Consistent with GMPs for DS
  - Identity, Purity, Strength, Composition and Limits of contaminants
Monograph submission

Requirements for submission:

- Test procedures
- Validation/verification procedures
- Stability data
- Product specifications
- Certificate of Analysis
- Chemical information of article and impurities
Scientific Liaison (SL):

- Evaluates the submission package
- Collects any additional information
  - Asks the sponsor for additional data or clarification
  - Collects additional information through available publications
  - Gets advice from Expert Committee (EC) Members*
- Drafts a preliminary forum proposal
- Works with Reference Standard (RS) scientist on the RS needed for the proposal

*EC Members are the volunteer standards-setting bodies at USP
The draft proposal is reviewed by
- Another SL
- Sponsor
- Assigned EC member
- Management

EC notification and comments
Forum Proposal is submitted for publication in *PF*

- Submitted for publications group with targeted PF issue (1-6)

Published for 90-day public comment period

Primary vehicle for public comments on proposals for the *USP-NF*

Freely available, online only since January 2011
All comments to any proposal in PF are tracked

Comments to proposals may require further action such as additional information from sponsor, additional information from commenter, etc.

SLs collects and evaluates all comments received, and shares them with the EC.

Queries/questions or clarifications are addressed and may not be considered as comments on proposal.
Expert Committee Ballot

- Depending on the comments, the monograph may
  - Advance to the ballot with no changes
  - Advance to the ballot with minor changes
  - Undergo revision and republication in PF

- Expert Committee votes to approve the monograph
  - Voting is done electronically
  - Each *USP-NF* Book and Supplement has its own ballot
  - Members with a conflict of interest are not allowed to vote
Vitamins with Minerals Oral Powder.

- Planned to be submitted to *PF 43 (6) – Nov.-Dec. 2017*
- Free online
- End of commentary period is January 31, 2018.
DEFINITION – Based on product specifications, CoAs & stability

Oil- and Water-soluble Vitamins and Minerals for Oral Suspension contain one or more of the following oil-soluble vitamins: Vitamin A as retinyl acetate or retinyl palmitate, Vitamin D as Cholecalciferol, Vitamin E as alpha Tocopheryl Acetate; one or more of the following water-soluble vitamins: Vitamin C as Ascorbic Acid or Sodium Ascorbate, Vitamin B1 as Thiamine Mononitrate, Vitamin B2 as Riboflavin or Riboflavine-5-phosphate Sodium, Vitamin B3 as Niacinamide, Vitamin B6 as Pyridoxine Hydrochloride, Vitamin B12 as Cyanocobalamin, and Folic Acid; and one or more minerals: copper, iodine, iron, selenium, and zinc, derived from substances generally recognized as safe and furnishing the elements in ionizable form. [NOTE—NMT 25% of elemental iron from the labeled amount may derive from ethylenediaminetetraacetic acid iron (III) sodium salt when used as source of iron.] Oil- and Water-Soluble Vitamins and Minerals for Oral Suspension contain NLT 90.0% and NMT 150.0% of the labeled amounts of Vitamin A as retinol equivalent (C₂₀H₃₀O), Vitamin D as cholecalciferol (C₂₇H₄₄O), and Vitamin E as tocopherol equivalent (C₂₉H₄₈O₂); NLT 90.0% and NMT 150.0% of the labeled amounts of Vitamin C as ascorbic acid (C₆H₈O₆), Vitamin B1 as thiamine base(C₁₂H₁₇N₄S), Vitamin B2 as riboflavin (C₁₇H₂₀N₄O₆), Vitamin B3 as niacinamide (C₆H₁₃N₂O), Vitamin B6 as Pyridoxine (C₇H₁₁NO₃), Vitamin B12 as cyanocobalamin (C₆₃H₈₈CoN₁₄O₁₄P), and folic acid (C₁₉H₁₉N₇O₆); NLT 90.0% and NMT 125.0% of the labeled amounts of copper (Cu), iron (Fe), and zinc (Zn); and NLT 90.0% and NMT 160.0% of the labeled amounts of iodine (I) and selenium (Se).
Vitamins with Minerals Oral Powder

**STRENGTH** - based on the tests validation procedures

- CONTENT OF VITAMIN A AND VITAMIN E - HPLC
- CONTENT OF VITAMIN D - UPLC
- CONTENT OF VITAMINS B1, B2, B3, B6 AND FOLIC ACID - HPLC
- CONTENT OF VITAMIN B12 - UPLC
- CONTENT OF VITAMIN C - HPLC
- CONTENT OF COPPER, IRON, SELENIUM, AND ZINC - ICP
- CONTENT OF IODINE - TITRIMETRY
Vitamins with Minerals Oral Powder

PERFORMANCE TESTS
- WEIGHT VARIATION OF DIETARY SUPPLEMENTS (2091)

CONTAMINANTS
- MICROBIAL ENUMERATION TESTS (2021)
- ABSENCE OF SPECIFIED MICROORGANISMS (2022)

SPECIFIC TESTS
- LOSS ON DRYING (731)

ADDITIONAL REQUIREMENTS
- PACKAGING AND STORAGE
- LABELING
General Notices: 3. CONFORMANCE TO STANDARDS

3.10. Applicability of Standards

“The standards in the relevant monograph, general chapter(s), and General Notices apply at all times in the life of the article from production to expiration. It is also noted that the manufacturer's specifications, and manufacturing practices (e.g., Quality by Design, Process Analytical Technology, and Real Time Release Testing initiatives), generally are followed to ensure that the article will comply with compendial standards until its expiration date, when stored as directed.”
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Thank You