Ensuring Quality Hand Sanitizer Production During COVID-19 Seminar

Formulating Quality Alcohol-Based Hand Sanitizer

Brian Serumaga, Ph.D.
Agenda

1. Overview of USP Compounding Standards
   - General Chapters
   - Compounded Preparation Monographs

2. Recommendations from the Compounding Expert Committee for Compounders during COVID-19 Pandemic public health emergency
   - Resources for compounding Alcohol-based hand sanitizer
1. Overview of USP Compounding Standards
USP was founded in 1820 by 11 physicians, in Washington, D.C.
The first Pharmacopoeia of the United States contained 217 of the “most fully established and best understood” medicines in the U.S. It was published “by the authority of the medical societies and colleges.”
Our people – USP’s global staff and volunteers

1200+ Staff

- United States: 58%
- Brazil: 4%
- India: 6%
- China: 4%
- Other global sites: Ethiopia, Europe, Ghana, Indonesia, Nigeria, Singapore: 28%

981 Scientific Experts, Volunteers, and Government Liaisons

- Scientific Experts: 981
  - 981: 53%
- Volunteers and Government Liaisons: 47%
  - 428 EC Members: 22%
  - 362 EP-Only Members: 18%
  - 191 Government Liaisons: 10%

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The 2020 – 2025 Council of Experts

Collaborative Groups

Biologics
- Biologics Monographs 1 - Peptides & Oligonucleotides
  - Michael De Felippis
- Biologics Monographs 2 - Proteins
  - Wendy Saffell-Clennner
- Biologics Monographs 3 - Complex Biologics & Vaccines
  - Earl Zablayckis
- Biologics Monographs 4 - Antibiotics
  - Matthew Brown
- Biologics Monographs 5 - Advanced Therapeutics
  - Mehrshad Aria

Small Molecules
- Small Molecules 1
  - Mary Seibel
- Small Molecules 2
  - Justin Pennington
- Small Molecules 3
  - Eric Krasien
- Small Molecules 4
  - Kim Haynh Fia
- Small Molecules 5
  - Amy Karen

Excipients
- Simple Excipients
  - Eric Munson
- Complex Excipients
  - Cefal Xoo
- Excipients Test Methods
  - Chris Monahan

General Chapters
- General Chapters - Dosage Forms
  - Martin Caffee
- General Chapters - Chemical Analysis
  - Nancy Leuen
- General Chapters - Microbiology
  - Donald Singer
- General Chapters - Packaging & Distribution
  - Rosalind Janes
- General Chapters - Measurement & Data Quality
  - Jane Wentzel
- General Chapters - Statistics
  - Charles Ten
- General Chapters - Physical Analysis
  - Watanabe Hie

Healthcare Quality & Safety
- Nomenclature & Labeling
  - Stephanie Crawford
- Healthcare Safety & Quality
  - Melody Ash

Dietary Supplements & Herbal Medicines, Food Ingredients
- Botanical Dietary Supplements & Herbal Medicines
  - Robin Marley
- Non-Botanical Dietary Supplements
  - Guido P. Faul
- Dietary Supplements Admission Evaluation & Labeling
  - Toreena Liao Fung
How we work

1. Public Health Need
   - Need identified by any stakeholder or USP
   - Need evaluated for possible standard development

2. Draft Standard
   - Best practices and scientific information collected

3. Public Comment Period
   - Draft standard published for stakeholder input

4. Review & Approval
   - Comments evaluated and addressed
   - Comments evaluated and further revision and comment needed

5. Publication
   - Final standard published with official date at least 6 months after publication

Stakeholder Implementation

USP Process
USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.

USP Expert Committee
- Healthcare Practitioners
- Academicians
- Healthcare Industry
- Regulatory Authorities (Non-voting Liaisons)
- Manufacturers

Stakeholders
- USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.
  - Healthcare Practitioners
  - Patients
  - Academicians
  - Healthcare Industry
  - Regulatory Authorities
  - Manufacturers
USP Standards for Compounding

USP provides 3 types of public standards for compounding

**USP General Chapters**
- establish practice standards to help ensure the quality of compounded preparations.

**USP Compounded Preparation Monographs**
- contain formulations for specific preparations for which there is no suitable commercially available product.

**USP Monographs for Bulk Substances and Other Ingredients**
- provide standards for identity, quality, purity, strength, packaging and labeling for bulk substances and other ingredients that may be used in compounded preparations.

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**Atenolol**

C$_{14}$H$_{22}$N$_2$O$_3$

Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl)-amino]propoxy]-:
2-[p-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl]-acetamide [2912-26-7].

**DEFINITION**

Atenolol contains NLT 98.0% and NMT 102.0% of C$_{14}$H$_{22}$N$_2$O$_3$, calculated on the dried basis.

Pour the Atenolol powder into a suitable container. Wet the powder with a small amount of Vehicle, and triturate to make a smooth paste. Add the Vehicle to make the contents pourable. Transfer the contents stay put to a calibrated container using the Vehicle. Add sufficient Vehicle to bring the Vehicle. Shake to mix well.
USP standards help promote public health, protect patients and healthcare workers, and address public health challenges.

- <795> Pharmaceutical Compounding – Nonsterile Preparations
- <797> Pharmaceutical Compounding – Sterile Preparations
- <800> Hazardous Drugs – Handling in Healthcare Settings
- <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, And Repackaging
- <1163> Quality Assurance in Pharmaceutical Compounding
- <1160> Pharmaceutical Calculations in Prescription Compounding
- <1168> Compounding for Phase I Investigational Studies
- <1176> Prescription Balances & Volumetric Apparatus Used in Compounding
- <1191> Stability Considerations in Dispensing Practice
History of <795>

- **First Nonsterile Compounding Standard**
  - USP <1161> *Pharmacy Compounding Practices* (1996)

- **General Chapter <795>**
  - Published in USP 24–NF 19 (2000)
  - Revised in USP 27–NF 22 (2004)
  - Revised in USP 34–NF 29 (2011)
    - Incorporated USP <1075> *Good Compounding Practices*
  - Revision Bulletin (2014) CURRENTLY OFFICIAL
    - Clarified that the BUDs in <795> are specific for nonsterile preparations and do not apply to sterile preparations
COMPOUND PILLS OF JALAP

Take of Jalap in powder; Rhubarb in powder; Castile soap, each one ounce. Submuriate of mercury six drachms and two scruples. Tartarized antimony, twenty eight grains. With water form a mass and divide into four hundred pills.
Components of a Compounded Preparation Monograph

- Title
- Definition
  - Lists the range of labeled amount of active ingredient
- Formula
  - Ingredients and quantities
- Compounding Procedures
- Stability-indicating Assay
- pH
- Packaging and Storage
- Labeling
- Beyond-use dates
  - Stability studies
  - General Chapters <795> or <797>

**ASSAY**

**SPECIFIC TESTS**
- pH (791): 3.6-4.6

**ADDITIONAL REQUIREMENTS**
- Packaging and Storage: Package in tight, light-resistant containers. Store at 2°-8° or at controlled room temperature.
- Beyond-Use Date: NMT 90 days after the date on which it was compounded when stored at 2°-8° or controlled room temperature.
- Labeling: Label it to indicate that it is to be well-shaken before use, and to state the Beyond-Use Date.
- USP Reference Standards (11)
  - USP Metronidazole Benzoate RS
2. Recommendations from the Compounding Expert Committee for Compounders during the COVID-19 pandemic
The CMP EC prepared resources as **recommendations** during the COVID-19 pandemic public health emergency.

These documents are for informational purposes only for healthcare practitioners and scientific professionals and are intended to address specific challenges during the COVID-19 pandemic.

These documents do not reflect the Compounding Expert Committee’s opinions on future development or revisions to official text of the USP-NF.

Parties relying on the information in these documents bear independent responsibility for, awareness of, and compliance with, any applicable federal, state, or local laws and requirements.

Developed outside the standard setting process = Not compendial standards

Based on expertise of the Compounding Expert Committee and Input received from stakeholders and
Compounding Alcohol-based Hand Sanitizers

- Stimulated by increased demand for hand sanitizers
- Based on CDC recommendations and WHO formulas
- Provided formulas with compounding instructions for:
  - Ethanol Antiseptic 80% Topical Solution
  - Isopropyl Alcohol Antiseptic 75% Topical Solution
- Provided recommendations for:
  - substitutions
  - calculations
  - addition of denaturants
- USP Compounding hand sanitizer toolkit
Need More Information?

Questions:

CompoundingSL@usp.org

Additional information:
https://go.usp.org/quality_hand_sanitizer
Thank You

Empowering a healthy tomorrow