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The USP Excipients Stakeholder Forum
Meeting #1
June 7, 2013



The Medicines Compendium

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USP Medicines Compendium

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Monographs
About the Medicines Compendium
General Chapters
General Notices/Guidelines



Public Quality Standards for Medicines Worldwide.
Global access and opportunities to contribute for all.

View Monographs

Featured Monographs

- **Rituximab 0.1:** For Development version posted July 24, 2012
- **Clarithromycin 0.2:** For Comment version posted July 10, 2012 . Comments end July 26, 2012.
- **Ritonavir 1.0:** Final Authorized version posted July 25, 2012

[View All Monographs](#)

Most Recent Monographs

- **Clarithromycin 0.3:** For Comment version posted July 26,

Join the Discussion

Make Your Comments Now

- **Mebendazole 0.2:** Comments end September 13, 2012.
- **Mebendazole Tablets 0.2:** Comments end September 13, 2012.
- **Valsartan 0.2:** Comments end September 19, 2012.

[View All Proposed for Comment Monographs](#)

New Discussion Forum Topics

- General Discussion on Tenofovir Disoporoxil Fumarate 1.0

NEWS AND ANNOUNCEMENTS

The USP MC welcomes you to the new 2.0 Website
Major improvements to the site include:

- Advanced Search and Navigation Features
- Online Commenting is enabled
- Online Discussion Forums are available for all Final monographs
- Inline Monograph Presentation

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- ▶ USP independently can create a monograph with reference materials
- ▶ MC is for medicines approved in any country and is applicable primarily to medicines legally marketed outside of the US
- ▶ MC is science based
- ▶ MC is authoritative, not official; the approval by the Council of Experts is what makes it authoritative.
- ▶ No separate labeling for reference materials, instead study any reference materials for one or more new uses. USP can synthesize impurities.
- ▶ It can help pharmacopoeias, including USP

- ▶ Contains Tests, Procedures, and Acceptance Criteria
- ▶ Tests are consistent with *USP-NF* (Identification, Assay, Impurities, Performance Tests, Specific Tests)
- ▶ Tests are grouped into one of three separate sections
 - Performance-Based Monograph (a framework for a monograph that includes critical quality attributes and acceptance criteria based on ICH Guidelines, but not specific tests and procedures)
 - Reference Procedures (A procedure that can be used to test any medicine, irrespective of source or route of synthesis)
 - Acceptable Procedures (containing procedures meeting the criteria of the Performance Based Monograph, but not those of a reference procedure)

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Healthcare Quality

Nomenclature,
Safety,
and Labeling
T. Reinders

Therapeutic
Information
and Formulary
Support
Chair, TBD

Compounding
G. Davidson

Reference Standards

Reference
Standards
M. Borer

General Chapters

Chemical Analysis
T. Wozniak

Biological
Analysis
W. Workman

Microbiology
J. Akers

Statistics
R. Singer

Physical Analysis
G. Amidon

Dosage Forms
J. DeMuth

Packaging
M. Foster

Toxicology
R. Osterberg

USP Chemicals

Small Molecules
Monographs 1
G. Van Buskirk

Small Molecules
Monographs 2
E. Parente

Small
Molecules
Monographs 3
B. Olsen

Small
Molecules
Monographs 4
M. Cutrera

USP Biologicals

B&B
Monographs 1
M. Mulkerrin

B&B
Monographs 2
J. Huxsoll

NF Excipients

Excipients
L. Block

Dietary Supplements and Foods

Dietary
Supplements
D. Gorecki

Food
Ingredients
A. Ebert

MC Chemicals

Chemicals (S. Asia)
A.R. Gomas

Chemicals (L. America)
I. Santoro

Chemicals (E. Europe)
Chair, TBD

MC Biologicals

Biologics
D. Patankar

MC Excipients

Excipients (E. Asia)
J. Tu

Herbal Medicines Compendium

S. Asia (India)
S.S. Handa

E. Asia (China)
Z.Qian