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# The *Medicines Compendium*

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# USP *Medicines Compendium: www.usp-mc.org*

# Key Points about the Medicines Compendium

- 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

# The *Medicines Compendium* Monograph

- 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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