

USP Forwards Proposed General Chapters on Topical and Transdermal Drug Products

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Two new draft USP General Chapters on Topical and Transdermal Drug Products have been published in Pharmacopeial Forum (PF) 35(3) May–June 2009. The General Chapters are <3> Topical and Transdermal Products—Product Quality Tests and <725> Topical and Transdermal Products—Product Performance Tests. Comments and suggestions for these tests and procedures are invited from interested parties through the routine PF comment process.

USP also is hosting a Workshop on the topic, to be held September 14-15, 2009, at USP Headquarters (for more information, go to [USP Workshops](#)). The Workshop attendees will discuss these two draft General Chapters, with an emphasis on addressing comments received and defining steps toward finalization of these two General Chapters.

A variety of chemical, physical tests and in-vitro release tests are used to assess the quality and performance of semisolid dose forms. The chemical and physical quality control tests that USP is proposing for a default monograph on these dose forms is presented in the draft General Chapter <3> Topical and Transdermal Products—Product Quality Tests. General Chapter <725> Topical and Transdermal Products—Product Performance Tests covers the apparatus and procedures used to evaluate the in vitro drug release and proposes a performance verification test to assess equipment performance. The product performance test is consistent with that proposed in the FDA Guidance for Industry, Nonsterile Semisolid Dosage Forms, Scale-up and Postapproval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vitro Bioequivalence Documentation (SUPAC-SS).

These two General Chapters are part of a series of chapters that will cover product quality and performance tests for the five routes of administration. In addition to the transdermal route, the other routes of administration include injection, mucosal, inhalation, and gastrointestinal. Draft General Chapter <3> is the first in the default monograph series. For oral dosage forms (gastrointestinal), <711> and Dissolution, <724> Drug Release are examples of product performance chapters.

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- [General Chapter <3> Topical and Transdermal Products—Product Quality Tests](#)
- [General Chapter <725> Topical and Transdermal Products—Product Performance Tests](#)
- [Stimuli Article, Topical and Transdermal Drug Products](#)