USP Has Revised New General Chapter <3> Topical and Transdermal Drug Products: Quality Tests; to be Republished in PF 36(6)

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USP is republishing the proposed General Chapter <3> Topical and Transdermal Drug Products: Quality Tests in Pharmacopeial Forum (PF) 36(6) [November–December 2010]. It originally appeared in PF 35(3) [May–June 2009]. To allow additional time for review of the revised proposed general chapter, USP also is posting it here in advance of its publication in PF. The general chapter is being republished because of the nature and significance of the comments received during the public comment period and at the USP Workshop on Topical and Transdermal Products, held at the USP headquarters on Sept 14–15, 2009.

The proposed general chapter covers physical-chemical tests for semi-solid topical dosage forms such as apparent viscosity, and uniformity in containers. For transdermal systems the adhesion, peel adhesion, release liner peel, probe tack, and leak tests were included.

Issues related to the drug product performance (in vitro drug substance release) will be addressed in a new General Chapter, <1724> Topical and Transdermal Drug Products: Performance Tests.

Comments and suggestions on the revised version of proposed General Chapter <3> are invited through the routine PF comment process.

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- Proposed General Chapter <3> Topical and Transdermal Drug Products: Quality Tests