

Quality Standards for Medicines, Supplements, and Food Ingredients throughout the World

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Dissolution (PVT Approach)

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<711> Changes and Implications

- Salicylic acid RS tablets have been removed as a requirement from <711>. Official December 1, 2009.
- The chapter now explicitly relies on the technical data sheet of each RS for the details regarding the PVT requirements.
- USPC is planning to use a geometric mean and standard deviation acceptance criteria when new lots are released. Timing to be determined.
- Calculation information will be on the technical data sheet accompanying the standards.
- The PVT calculation toolkit will be also available online to be used to evaluate the PVT test results



Prednisone PVT-RS

- A new lot of the Prednisone PVT-RS will be released on the market soon
- Collaborative study on the new lot was finalized in Aug. 2009
- The evaluation of the acceptance ranges for the now lot is currently in progress



Topical/Dermal

- USPC published a Stimuli article and draft chapters on quality and testing requirements for topical and dermal products in Pharm. Forum 35(3).
- Draft chapter <3> outlines proposed quality testing requirements. Available at <http://www.usp.org/pdf/EN/USPNF/transdermalGenChapter3.pdf>
- Draft chapter <725> outlines a proposed product performance test (vertical diffusion cell) and a PVT standard (1% hydrocortisone cream) for semisolid dosage forms (cream, ointment, gel). For TDS products, continuing use of USPC 5, 6 and 7 is recommended. Available at <http://www.usp.org/pdf/EN/USPNF/transdermalGenChapter725.pdf>
- Workshop September 14 and 15 to discuss chapters and comments received.
- These chapters could serve as models for parallel ones for other routes of administration.



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Thank You!



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