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Changes to the Dissolution Performance Verification Test

Official December 1, 2009

Beginning December 1, 2009, the Performance Verification Test (PVT) using Salicylic Acid Tablets RS is no longer required for USP Apparatus 1 and 2. The tests using the Prednisone Tablets RS tablets for USP Apparatus 1 and 2 and Chlorpheneramine Maleate Extended-Release Tablets RS for USP Apparatus 3 are still required. The testing procedure and the acceptance criteria for the PVTs are given in the respective Technical Data Sheets for the current lots of the reference materials. The current lot of Prednisone Tablets RS is P0E203; that for Chlorpheniramine Maleate Extended-Release Tablets RS is G0B259.

Also beginning December 1, 2009, the change in General Chapter <711> removing the requirement for individual tablet tests for the PVT becomes official. This is not a change in the PVT procedure or criteria. The chapter will instead rely on the Technical Data Sheet provided with the particular lot of RS to provide the acceptance criteria. This change to <711> allows USP, via the Technical Data Sheet, to move from acceptance criteria for the individual tablet results to a new set of criteria at a later date, as detailed below.

USP is working on new lots of the Prednisone Tablets RS and Chlorpheniramine Maleate Extended-Release Tablets RS. Concurrent with the release of each of the new lots, USP will, for that reference material, move to dissolution PVT acceptance criteria using the geometric mean and %CV obtained from the dissolution results from a pre-defined number of tablets. The concepts and procedures for the new PVT criteria were provided in a Stimuli to the Revision Process article entitled, Description of the Upcoming change in Data Analysis for USP Dissolution Performance Verification Tests, *PF* 34(6) [November-December 2008]. The new testing procedure and the acceptance criteria will be provided in the Technical Data Sheet accompanying the new lots of the reference material. In recognition that any such change will require adjustment of internal laboratory documentation and procedures, USP will provide the details of the new approach on this website soon after approval by the relevant USP Expert Committees. Prior to a new lot's release, USP will also provide an on-line compendial tool to assist with the calculations.

[For more information, contact RS Technical Service at rstech.usp.org]