

**USP Position
The USP Performance Test
Systems Suitability Studies
September 24, 2005**

Dosage Form Performance Test

USP emphasizes the importance of the Performance test in the public or private specification for a dosage form. For non-solution orally administered dosage forms, elements of the USP Performance test procedure for dissolution are provided in General Chapter <711> and for disintegration in General Chapter <701>. Given that these are the only tests that may be applied to assess performance of a dosage form over many decades of manufacture, reduced reliance on the dissolution procedure would be contrary to the public health. USP is expending considerable resources to expand the USP Performance test to other dosage forms and drug delivery routes.

Systems Suitability Studies

For many compendial procedures, including the USP dissolution procedure, USP emphasizes the importance of a Systems Suitability study. General approaches for these studies are described in <1225> and, for dissolution, in <711>. USP recommends a chemical calibrator based Systems Suitability check at periodic intervals. Manufacturers generally choose to execute this test twice yearly. USP supplies official USP Calibrator Tablets, Salicylic Acid Tablets (Dissolution Calibrator, Non-disintegrating), Prednisone Tablets (Dissolution Calibrator, Disintegrating), and Chlorpheniramine Maleate Extended-Release Tablets (Drug Release Calibrator, Single Unit). Official USP calibrators are an integral part of a Systems Suitability check that assesses all elements of a dissolution procedure (tester, analyst, analytical procedures).

New Calibrator Lot

At this time, USP is advancing a new lot of prednisone calibrator tablets (Lot P). The topic of Dr. Hauck's presentation will be the proposed collaborative study for this new lot. Dr. Hauck will also address certain issues that arose during the deliberations of the ACPS at its May 2005 meeting. Finally, Dr. Hauck will discuss some alternative approaches to the analysis of results of a Systems Suitability study. USP believes these alternative approaches, if adopted, may avoid a problem with 'multiple-comparisons' for the current Systems Suitability study.

Further Work

An alternative to a chemical calibrator-based Systems Suitability study is a mechanical-calibration Systems Suitability study. Mechanical calibration is a time-consuming approach (as is a calibrator-based Systems Suitability study) and does not assess the entire system but rather the tester itself.

Engineering approaches that allow direct measures of heat transfer and/or shear caused by vessel fluid flow may be developed as surrogates for mass transfer in the confirmation of standard conditions in a dissolution test system. These approaches could potentially become alternative systems suitability standards.

USP believes that a science based understanding of the merits of each type of approach (chemical based, mechanical based, engineering based) should be possible and looks forward to engaging with stakeholders in further research and discussion.