

MEDIA RELEASE

SOTAX introduces the USP Apparatus 4 Dialysis Adapter for Drug Release Testing from Liposome and Nanoparticle Formulations

August 2011: The SOTAX Group, the market leader and pioneer in USP Apparatus 4 announce the release of a new Dialysis Adapter for use with the SOTAX CE7smart Flow Through Dissolution System.

The patented A4D was designed and tested in collaboration with Professor Diane Burgess of the School of Pharmacy at The University of Connecticut. The adapter was designed to fulfill a growing application requirement for drug release testing from controlled-release parenteral products such as liposomes and nanoparticle formulations.¹ Dr. Burgess's work on in-vitro drug release testing using USP Apparatus 4 began several years ago with the study of microsphere formulations.²

The challenges with monitoring drug release from these formulations are sample containment, filtration, and method standardization. Traditional small scale drug release testing on liposomes began with non-compendial sample and separate, dialysis sac, and diffusion cell techniques. In order to incorporate this into the USP 4 method, an adapter was designed which uses dialysis tubing fit over a compartment within the standard 22.6 mm flow cell. This new adapter allows researchers to accurately discriminate different liposome formulations and defines a standardized approach to dialysis testing. SOTAX is a proud sponsor of The School of Pharmacy at the University of Connecticut. In late 2009, the University of Connecticut honored SOTAX with the dedication of the "SOTAX Dissolution and Drug Release Testing Laboratory" at UCONN.

For more information about the A4D Dialysis Insert and USP Apparatus 4, please contact us.



¹ Bhardwaj, U., Burgess, D.J., 2010. A novel USP apparatus 4 based release testing method for dispersed systems. *Int. J. Pharm.* 388, 1-2, pp. 287-294.

² Rawat A, Stippler E, Shah VP, Burgess DJ. 2011. Validation of USP apparatus 4 method for microsphere in vitro release testing using Risperdal(®) Consta(®). *Int J Pharm.* 2011 Aug 24