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New FLUX technology from Pion adds real-time, IVIVC absorption prediction to dissolution testing

New for AAPS 2016, MicroFLUX and MacroFLUX testing technology give developers reliable absorption data for APIs, formulations and finished dosage products

Billerica, MA, USA – October 18, 2016 – Pharmaceutical scientists have long sought a reliable method for predicting the absorption potential of finished dosage products prior to clinical trials, but have been frustrated by the limitations of standard dissolution testing, which cannot predict the *in vivo* response to drug products due to the complex interplay of solubility and permeability in the human body. Now, for the first time, new FLUX testing technology from Pion combines traditional dissolution testing with a repeatable method for assessing the absorption potential of APIs, API/ingredient combinations, or finished dosage products. The result is a single combined test that makes more reliable and realistic IVIVC (*in vitro-in vivo* correlation) testing and modeling possible.

The FLUX testing technology consists of a traditional USP I or II stirred dissolution chamber, which acts as a donor vessel, but adds a stirred receiver vessel containing Pion ASB (acceptor sink buffer) solution. Between the two vessels is a PION Pampa GIT artificial membrane, which mimics the behavior of the gastrointestinal wall. As the concentration in the dissolution chamber rises, absorption through the membrane into the receiver solution is monitored simultaneously, using *in situ* fiber optic UV detection probes. Continuous data collection of the concentrations in both vessels provides the required data density for accurate assessment of both dissolution and transmembrane absorption, or flux.

“By using FLUX technology, pharmaceutical developers can derive far more intelligence from a dissolution assay than ever before, says Dave Kwajewski, VP sales and marketing for Pion. “Not only can they use it to identify potential problems with the permeability and absorption potential of a promising compound far earlier in the development process, but to evaluate the absorption potential and predict bioequivalence of various finished dosage products. With FLUX technology, clinical trial failures due to unknown absorption problems can be a thing of the past.”

The performance of the FLUX testing technology has been validated in a recent *Molecular Pharmaceutics* article titled “Investigation and Mathematical Description of the Real Driving Force of Passive Transport of Drug Molecules from Supersaturated Solutions.”

Pion FLUX testing technology is available in two sizes: MicroFLUX is ideal for assessing early-stage APIs and unformulated combinations in small-volume tests of 20 ml or less, while MacroFLUX is sized to evaluate the dissolution and absorption performance of finished dosage products in volumes of 500ml, 900ml, or 1l.

MicroFLUX™ testing technology is an add-on option to the µDISS Profiler™ instrument (Pion Inc.), which consists of four pairs of temperature controlled side-by-side diffusion chambers mounted on top of a stirring

platform. Each pair consists of a donor and a receiver compartment separated by a filter-supported GIT-optimized artificial membrane (Double-Sink™ PAMPA 2).

About Pion Inc.
Pion Inc. develops and manufactures instrumentation for compound testing in pharmaceutical R&D. These include high-precision fiber optic-based analytical instruments for solubility and dissolution measurements and complete systems for permeability (PAMPA), solubility, and ionization. Pion also provides CRO services for solubility, permeability, dissolution, pKa, and lipophilicity testing, as well as new Field Services for maintenance, calibration and repair of all leading brands of laboratory equipment. More information is available at www.pion-inc.com.

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