Pion
Rainbow

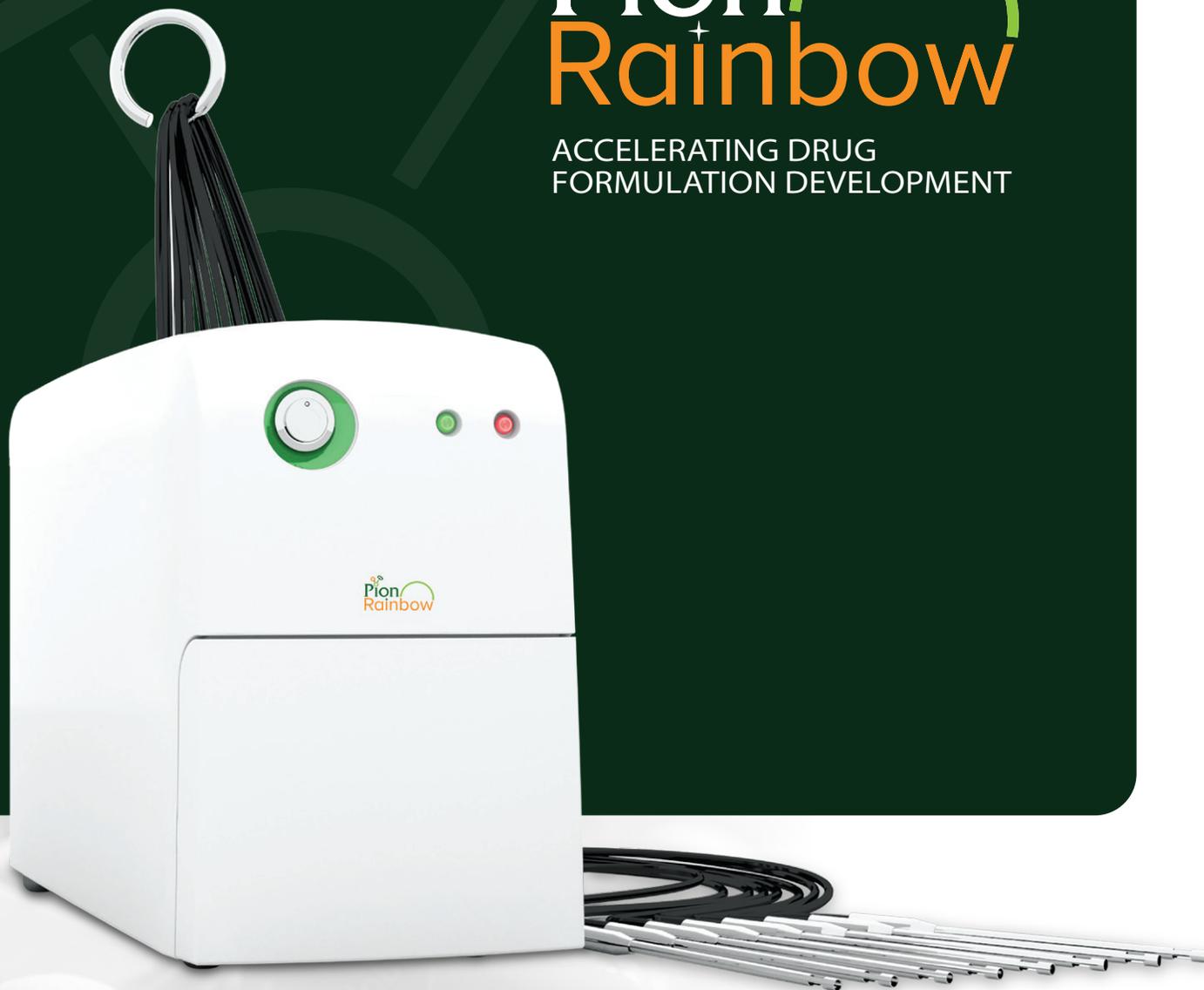## ACCELERATING DRUG
FORMULATION DEVELOPMENT

POWERING DISCOVERIES.

Pion

Rainbow Dissolution and Permeation Portfolio

An *in vitro* analytical platform for dissolution and permeation measurements from API screening to whole dose formulations.

The Rainbow R6™ Fiber Optic System is an *in situ*, UV-VIS spectrometer with 8 independent channels which measures dissolution and permeation in real-time.

Pion's Rainbow R6 portfolio provides real-time concentration monitoring even in complex media, allowing you to accelerate robust formulation development, derisk outcomes and predict *in vivo* performance with confidence.

Real-time, Robust Insights

Pion's Rainbow R6 delivers real-time concentration measurements using fiber-optic probes with variable path length, enabling highly accurate analysis even for weakly absorbing or poorly soluble compounds. Fully automated, *in situ* measurements eliminate the need for sampling, filtration, solvent use, or sample consumption required by traditional HPLC methods.
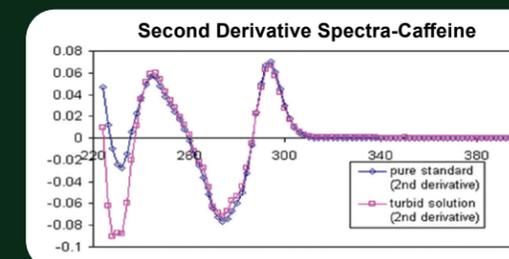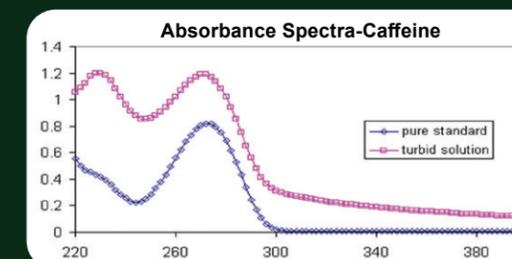
No Filtering No Sampling

Accuracy in Complex Media and Turbid Samples

By measuring directly in the test medium, Rainbow overcomes the limitations of conventional UV spectroscopy in complex or turbid systems. Pion's AUPRO™ software applies 2nd derivative and advanced baseline correction algorithms to compensate for light scattering, enabling reliable concentration quantification under biorelevant conditions.

Absorbance Spectra-Caffeine

- pure standard
- turbid solution

Second Derivative Spectra-Caffeine

- pure standard (2nd derivative)
- turbid solution (2nd derivative)

Small Volume Dissolution

The Rainbow R6 can be used in multiple configurations. For small volume dissolution monitoring where only small quantities of API are available, the microDISS Profiler™ and the miniDISS Profiler™ are ideal.

The microDISS Profiler system consists of a Rainbow R6 and the MB8 small volume dissolution bath. It allows testing in media volumes as low as 2 mL to 20 mL. With small amounts of API to run a dissolution study, the MicroDISS Profiler allows 100X less volume needed than a traditional USP apparatus.

The miniDISS Profiler system consists of a Rainbow R6 and the miniDT™ dissolution tester, designed to replicate biorelevant conditions for final oral doses, and can be used with media volumes from 40 mL to 250 mL.

MicroDISS Profiler system

MiniDISS Profiler system

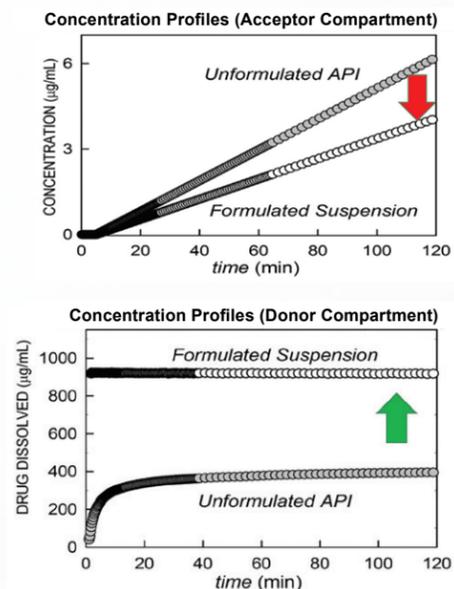## Solubilization Is Critical for Bioavailability, So How Can You Enhance Solubility in Your Formulation?

Drug formulation optimization utilizes multiple techniques to enhance dissolution and solubility including:

- Salts
- Cosolvents
- Nanoparticles
- Cyclodextrins
- Cocrystals
- Surfactants
- Amorphous solid dispersions
- Lipid-based formulations

Increased solubility does not always lead to increased absorption of your API. Measuring dissolution and permeation with Pion's Flux technology provides insight into the effects of a solubility enhancement strategy on overall formulation performance.

A formulation is compared to the pure API in this dissolution-permeation study. While the dissolution was improved by 2-3 times by the formulation strategy, the permeation/flux decreased significantly, causing an overall lowered concentration of the formulated API in the receiver compartment, demonstrating a clear example of solubility-permeability interplay.

The graphs to the right demonstrate a clear example of solubility-permeability interplay in formulation development.

Concentration Profiles (Acceptor Compartment)

Unformulated API

Formulated Suspension

CONCENTRATION (μg/mL) vs *time* (min)

Concentration Profiles (Donor Compartment)

Formulated Suspension

Unformulated API

DRUG DISSOLVED (μg/mL) vs *time* (min)

Pion Pioneered Permeability Measurements

Pion pioneered permeability measurements of APIs and formulations through artificial membranes that mimic the human gastrointestinal tissue. Pion's innovation includes a novel PAMPA solution, a Parallel Artificial Membrane Permeability Assay for high through-put screening.

Pion's PAMPA method delivers a biometric model based on a biorelevant, lipid-coated membrane, specific assay reagents, and testing under controlled stirring conditions. Pion's method has been validated against cell-based, animal and human data, and the same proprietary technology is used in the FLUX configurations of the Rainbow Dissolution & Permeation Portfolio.

Rainbow R6 FLUX Configurations

Pion's FLUX technology provides simultaneous dissolution and permeation measurements at all stages of pharmaceutical development, enabling biorelevant absorption analysis to drive smarter oral formulation optimization. FLUX is recommended for studying excipient and food effects, as well as to predict bioequivalence and rank formulations prior to *in vivo* testing.

MicroFLUX
Rainbow R6, MB8, and MicroFLUX vessels

Media Volume: 16-20 mL

Early stage rank ordering

MiniFLUX
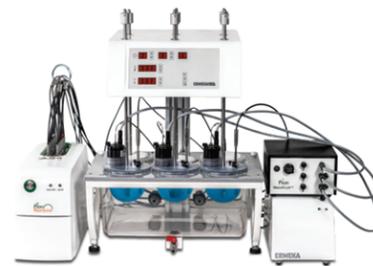Rainbow R6, MiniDT, and MiniFLUX vessels

Media Volume: 180-250 mL

Formulation development with limited API

BioFLUX
Rainbow R6, external USPII bath, stirring unit and BioFLUX vessels

Media Volume: 200-500 mL

Analysis of whole dose formulations in biorelevant volumes

MacroFLUX
Rainbow R6, external USPII bath, stirring unit and MacroFLUX vessels

Media Volume 800-1000 mL

Standard USP testing in late-stage development

Combined dissolution and permeation analysis to understand absorption—driving smarter oral formulation optimization.

In Vitro + *In Silico*: Predictive Modeling

Pion's Predictor software module applies the mechanisms of the Gastrointestinal Unified Theoretical (GUT) framework to convert *in vitro* flux data to predictions of *in vivo* oral absorption and percent fraction absorbed (FA%).

Predictor classifies APIs according to the Biopharmaceutics Classification System (BCS), and assigns an estimation of the rate limiting step to absorption based on permeability, dissolution or solubility-permeability limitations to help formulators optimize their candidates for greatest chance of clinical success.

Pion
Predictor
Powered by the GUT Framework

Rainbow R6 and SCISSOR N3

Gain biorelevant data about your subcutaneous sample *in vitro*

SCISSOR N3™ is an *in vitro* subcutaneous injection site simulator that accelerates rank-ordering and excipient screening for injectable drug development. Coupled with the Rainbow R6, the platform enables true, real-time, post-injection release data while avoiding the lag and degradation risks of offline analysis. Beyond primary release profiles, Rainbow can also detect concentrations of additional UV-active components and flag possible post-release stability issues, leading to better insights, faster.

Rainbow R6 and SCISSOR N3

DissoSpec QC Dissolution Monitoring System

Dissolution data – now live!

Unlike traditional dissolution systems which are often combined with offline measurements, Pion's DissoSpec™ system gets real-time data and fully integrated reporting. The instrument has the ability to take frequent data points to characterize complete dissolution profiles, enabling the development of a validated method for transfer to QC.

Real-time measurements from the *in situ* fiber optic probes greatly simplify experiments. For quick-release and extended-release formulations, you can now capture all of the data you need without operator intervention.

Rainbow Accessories and Specifications

Software Requirements

- PC or laptop with Windows 11, 64-bit operating system and minimum 2.3 GHz microprocessor, 8 GB RAM, 10 GB of free disk space (16 GB or higher storage recommended), one free USB port, and Microsoft Excel for data export
- AuPRO data acquisition and processing software

Probes

- Rainbow R6 instruments are supplied with one fiber optic straight probe and 3 interchangeable probe tips (2,5,10 mm path length) for every channel.
- Optional probe configurations include J-probes, long 33 cm probes, and additional tips of 1 mm and 20 mm path length.
- FLUX configurations include one fixed path length angled probe per channel (excludes microFLUX).
- SCISSOR N3 Fiber Optics Probe which is a fixed path length straight probe used for analysis in the Scissor N3.

Technical Specifications

- Light Source: Deuterium
- Optimal wavelength range of Deuterium lamp: 240-500 nm
- Nominal PDA detector wavelength range: 200-720 nm
- Baseline flatness $</= 0.002$ AU within the range 240–600 nm
- Noise $</= 0.002$ AU at 600 nm
- Stability $</= 0.002$ AU at 270 nm
- Stray light $</= 1\%$
- Wavelength accuracy in UV region ±1 nm, in visible region ±2nm.
- Absorbance Range: up to 2 AU
- Minimum Sampling Interval: 2 seconds

Learn more at **pion-inc.com**