

## Rainbow™

*The Rainbow is a powerful tool for accurate dissolution analysis without the high cost, extensive maintenance, operator involvement, and slow turnaround time of conventional methods. Fiber optic UV-spectroscopy has been adopted for dissolution testing by R&D, manufacturing, and QC laboratories worldwide.*



The Rainbow's real time *in situ* dissolution testing method surpasses traditional batch HPLC and on-line flow UV systems by eliminating high maintenance equipment, sipping mechanisms, wasted bench space, and expensive solvents.

The Rainbow employs a patented process for acquisition and dynamic presentation of data. This enables the user to view the dissolution curve, from each probe, in real-time. Equipped to collect data from the very start of the experiment to several days later, the Rainbow monitor is ideal for both rapid-release and extended release solid dosage forms.

### **Small, Clean, and Quiet**

The Rainbow fits on your lab bench right next to the dissolution bath. Since the Rainbow pipes the light and not the liquid, it does not generate any waste of its own. In fact, the only cleaning required is a quick rinse of the probes. Using the accompanying Indigo™ software, the Rainbow is easy to operate, requiring almost no maintenance, as there are no moving parts in the system.

### **UV Dip-Type Probes**

The Rainbow utilizes dip-type UV probes (6 to 8 per monitor) to measure the amount of active pharmaceutical ingredient (API) released from a solid dosage form. These probes are suspended at the USP sampling position in the dissolution vessels and reside *in situ* for the duration of the test. Constructed of stainless steel, the probes have interchangeable quartz mirror tips offering path lengths of 1, 2, 5, 10, and 20 mm. The probes are sturdy, durable, and may be used in most dissolution media and all baths.

## Photo Diode Array Spectrometers

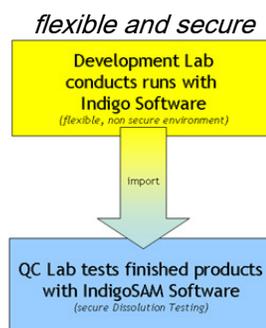
The system uses Zeiss UV spectrometers dedicated to each dip probes for optical sampling. This allows rapid acquisition of full UV spectra from 200 nm to 450 nm, in steps of 2 nm, from all vessels. In the case of a controlled-release formulation, a typical system configuration might acquire spectra every 20 minutes for 24 hours. For an immediate-release formulation, spectra may be taken every 2 seconds or faster.

The Rainbow exhibits excellent analytical precision in the range of 0.001 to 2.0+ absorbance units. The low thermal expansion properties of the titanium body virtually eliminate drift due to ambient temperature fluctuations. The patented design of the PDA UV spectrometer eliminates moving parts and ensures high wavelength accuracy and precision with annual drift of < 0.1 nm.

## IndigoSAM Security for the QC Environment

For GMP and QC environments, the optional IndigoSAM™ secure account manager for Indigo™ adds a full suite of security tools commonly employed in GMP and 21 CFR Part 11 laboratories.\*\* These include secure user access, audit trails, digital signatures, data security and secure reporting. An optional validation package provides full documentation of IndigoSAM software functionality.

### Indigo Works Seamlessly with IndigoSAM



### System Suitability Must Pass Test Limits Before Conducting a Dissolution Run

	Scan Std A Conc: 0.011 mg/mL 5 Scans, RSD threshold: 2.0				Scan Std B Conc: 0.0111 mg/mL 3 Scans, RSD threshold: 2.0			
	Channel 1	Channel 2	Channel 3	Channel 4	Channel 5	Channel 6	Channel 7	Channel 8
A	✓ 0.20	✓ 0.14	✓ 0.25	✓ 0.16	✓ 0.31	✓ 0.24	✗ Pass/Fail	✗ Pass/Fail
B	✓ 0.07	✓ 0.21	✓ 0.03	✓ 0.16	✓ 0.50	✓ 0.12	✗ Pass/Fail	✗ Pass/Fail
%D	✓ 0.03	✓ 1.29	✓ 0.77	✓ 0.81	✓ 0.53	✓ 1.03	✗ Pass/Fail	✗ Pass/Fail

Users, Methods, Data and Reports are Documented with a Unique, Secure Digital Certificate

The text above this line is signed by the  
 Indigo Digital Signature  
 PutWGseqbyBRRuJBySDMh0iZo7GgH1XVFRKzemaGhPpJbHXvQQF6IwCuN1N7AID8QPfahuvJG5qQyHPXxMsJmdQ3Lr5t0T4/XAr+y7H/pY6ycG6+o2b9GPsnhGk  
 HyjP8f+4ZBz38GQ4osRDvmaJvAEQKCEVyzYNtYeqbzCRo318V4=

**\*\*Compliance within the IT environment is the sole responsibility of the user.**

## Patents and Trademarks

Pion's methods and products are protected by multiple U.S.A. and foreign patents with several patents pending. Spectra, Rainbow, Indigo and IndigoSAM are trademarks of Pion Inc.