



Spectra™

The Spectra is designed for accurate, real-time, maintenance-free QC dissolution testing. IndigoSAM™ software satisfies the needs of both lab chemists and technicians working in 21 CFR Part 11 regulated labs. This new system maximizes value without sacrificing performance. With the Spectra, technicians can perform dissolution testing confident that their data will not be compromised by plugged filters or lines in the middle of a QC run.



The Spectra measures the API (active pharmaceutical ingredient) concentration in real-time using fiber optic probes immersed in the dissolution vessels. While the traditional approach of removing liquid samples from the vessels is prone to plugging and requires frequent maintenance, the Spectra collects the entire UV-vis spectrum (200-720 nm) directly from the solution and displays concentration data in real time.

The result is a very simple, rugged and reliable instrument that displays concentration as it is generated, day after day, run after run. Real-time dissolution data translates directly into faster response and manufacturing process feedback. In actual use, the system has performed flawlessly in laboratories that conduct sustained release tests requiring up to 45 or more days. Many studies have shown excellent agreement with HPLC measurement.

Breaking the Barriers

With its redesigned optical bench and cost competitive pricing, the new Spectra delivers a simplified, robust, fiber optic system into laboratories that could previously consider only conventional liquid sampling. The Spectra has few moving parts, solarization-resistant optical fibers, a long-life xenon lamp, and the renowned, rock-solid photodiode array (PDA) from Zeiss.

Great Value and Performance without Compromise

With a small footprint, the Spectra fits right next to the dissolution bath. Since the Spectra pipes the light and not the liquid, no waste is generated. A quick rinse of the probes is the only cleaning required. The Spectra exhibits excellent analytical performance in the range of 0.001 to 2 absorbance units. The photodiode array spectrometer eliminates moving parts and ensures high wavelength accuracy and precision over time. Annual calibration is a simple and rapid procedure.

Real-Time Dissolution Monitoring

Pion's patented real-time dissolution monitoring rapidly captures UV-Vis spectra of the drug in solution every 30 seconds. There is no waiting for results as with online systems. The rapid data capture rate ensures a much higher data density to characterize the dissolution profile.

Flexible Features

The Spectra utilizes stainless steel dip-type fiber optic probes (up to 8 per monitor) with interchangeable quartz mirror tips. The probes are suspended at the USP sampling position in the dissolution vessels. Depending on the API dosage, tips with path lengths of 1, 2, 5, 10, or 20 mm can be chosen to maximize linear response. Other systems require separate probes for each pathlength; an expensive design. Pion probes are sturdy, durable, and may be used in most dissolution media and all baths.

Indigo™ for Method Developers

Indigo™ software has been specifically designed to provide the tools and environment required by method developers, enabling the flexible, rapid evaluation of parameters to maximize accuracy and performance. Users can select from a variety of algorithms (height, area, etc) to provide accurate quantitation even in the presence of high turbidity. Raw and processed data can be exported into Microsoft Excel format for additional operations, if required.

IndigoSAM™ Security for the QC Environment

For GMP and QC environments, the optional IndigoSAM™ secure account manager software adds a full suite of tools enabling 21 CFR Part 11 compliance.** The IndigoSAM™ software provides a range of user roles and available tasks, specifically geared to the responsibilities of each. Features also include password protected user access, audit trails, secure data storage, digitally signed reports and more. The software is intuitive and very easy to operate, even for occasional users. On-screen instructions guide the operator through the method steps including system suitability, dissolution test run, results review, and reporting.

****Compliance within a specific IT environment is solely the 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.

