Fiber Optic Solution for QC Dissolution Testing

Fiber optic dissolution testing offers you a fast and cost-effective method for determining the rate of release of a drug product over time. With 21 years of industry leadership, Pion's fiber optic technology delivers benchmark performance and reliability.

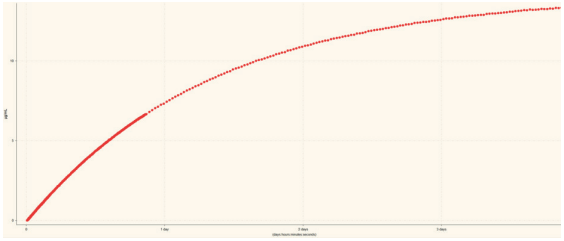
Our powerful analytical instruments and 21 CFR Part 11 compliant software measure concentration and percent dissolved data in real time and are widely trusted in quality control labs, both for accuracy and efficiency.

Why Fiber optics?

In-situ real time fiber optics hold many advantages over traditional methods that involve sampling, fluidics/sample handling, and offline analysis.

In-situ Benefits:

- No filtration
- No pumping
- No sampling
- Dissolution profile with frequent data points (as quickly as every 5 seconds)
- Real-time dissolution curve for every channel, up to 8 channels

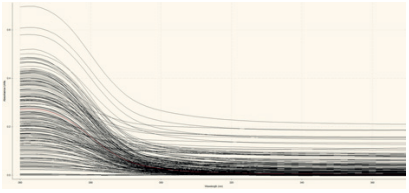


What does *in-situ* mean?

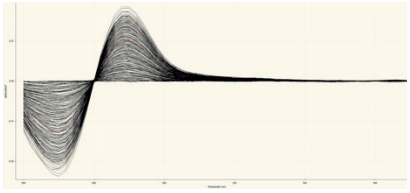
Fiber optic systems share a majority of elements with conventional UV spectrophotometers. The difference is that instead of drawing a sample and transferring into a cuvette and then the cuvette being inserted in the spectrophotometer for analysis, the *in-situ* fiber optic probes allow light to travel directly to and from the dissolution apparatus and analyses are performed directly in the dissolution baths within the windows of the fiber optic probes themselves. No sampling, no handling, no analysis delays.

Does it work in turbid media?

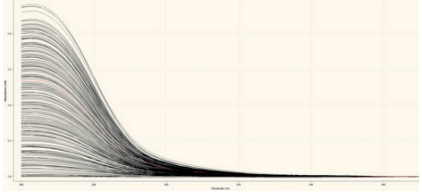
We provide a range of advanced mathematical approaches to correct the spectral data for turbidity including 4 different baseline correction methods and advanced second derivative spectum analysis.



Direct spectrum; untreated



2nd derivative spectrum; corrected



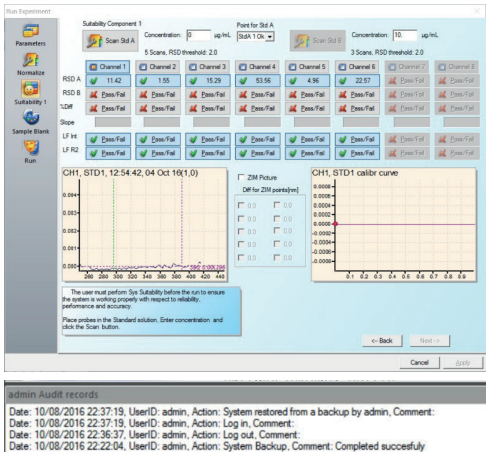
Direct spectrum; corrected

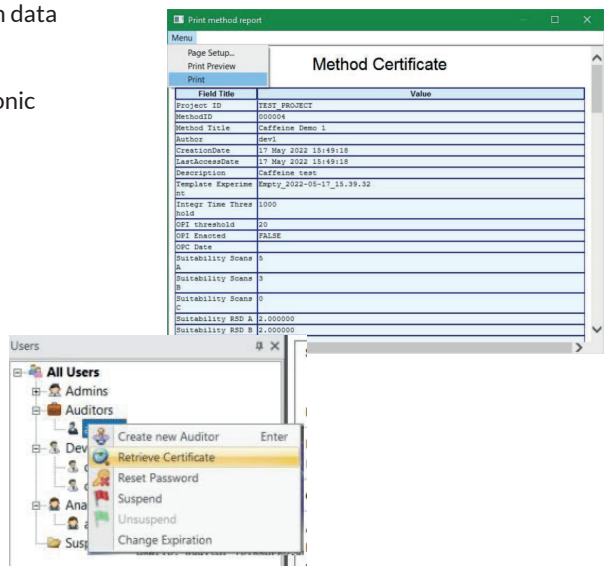
Hardware

- The Rainbow R6 Concentration Monitor is a spectrometer that can measure up to 8 channels independently and in real-time. The photodiode array detectors measure from 200 to 720 nanometers
- The fiber optic probes are submerged directly into the dissolution vessels and measure the UV absorption profile of your API as frequently as every 5 seconds and for as long as 28 days or more for extended release drug products

Software

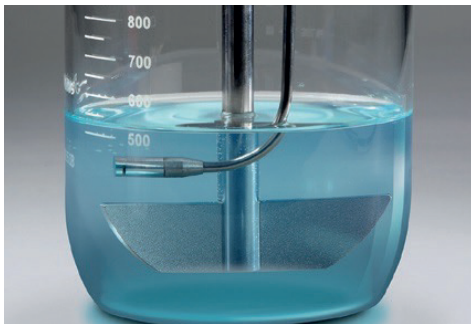
- Straightforward and powerful platform to collect dissolution data
- Can be integrated into 21 CFR Part 11 environment
- Key features of the software include: secure records, electronic signatures, audit trail, user security





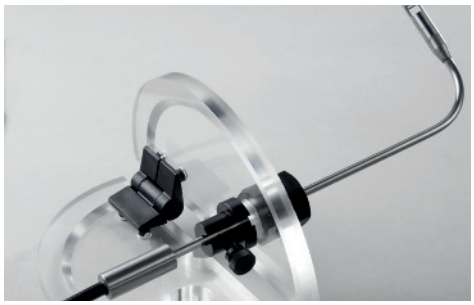
Integration - Working with your dissolution bath

- Compatible vessel covers are available (off-the-shelf or custom) whenever the bath design allows the integration
- Multiple probe designs are available (straight or J-style; fixed or variable pathlength) to optimize the data collection
- Broad pathlength range (1-20 mm) is available to fit the system to the desired concentration range



Documentation – fitting into your compliant environment

- Clear definition of features/functions relating to 21 CFR Part 11 are provided in the design specifications and functional specifications documents developed with a computer system validation specialist.
- Software and hardware qualification is provided through detailed IQ/ OQ/PV protocols.



Pion

Pion stands behind the science

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Specifications subject to change without notice
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