

INTRODUCING THE

Pion DissoSpec™ QC Dissolution Monitoring System



DissoSpec is an integrated, *in situ* UV-Vis dissolution testing system for efficient and compliant method development and Quality Control (QC) dissolution analysis.

Dosage to Data, Simplified

Unlike traditional dissolution systems whose components operate independently, the Pion **DissoSpec** provides real-time data and fully integrated reporting. Analytical Development scientists will appreciate the ability to take frequent data points to characterize complete

dissolution profiles to develop a validated method for transfer to QC. Real-time data from the *in situ* fiber optic probes greatly simplify experiments. Whether samples are quick release or extended release, **DissoSpec** simplifies data collection and interpretation.

The Pion **DissoSpec** Advantage:

Simplified QC with No Pumps, Filters, or User Bias

No Sampling

Direct, in-vessel measurement eliminates accuracy risks associated with differences between collected samples, media replacement errors, filter sample retention and offline sample degradation.

Reduced Analyst Variability

Automated *in situ* data analysis accommodates multi-shift or multi-user scenarios, reducing variability and ensuring consistent results.

Minimal Maintenance

Avoid complex sampling systems and frequent component replacements, saving time and costs.

Semi-automated System

Press "start" and let it go with walk-away automation.

Simplified Workflow

At the end of your dissolution experiment, come back to a complete and integrated report.



The Pion **DissoSpec** is a dissolution test system designed to simplify QC release testing. The system integrates UV-Vis technology in each dissolution vessel, enabling real-time data collection and rapid decision-making while eliminating traditional sampling equipment like pumps, syringes, and filters. **DissoSpec** is engineered to meet USP 1 / 2 / 5 / 6 dissolution methods, ensuring compliance while reducing operational costs.

System Highlights



Advanced UV-Vis Technology

- **Rainbow® R6 Dynamic Dissolution Monitor System for Multi-channel UV-Vis Detection:** Robust, *in situ* analysis with no moving parts, ensuring stable, reliable data collection.
- **In situ Data Acquisition:** Acquire full spectra readings as fast as every 5 seconds, providing immediate insight into dissolution progress.
- **2nd Derivative Spectroscopy:** Quantify and resolve dual-component dosages accurately without filtration or physical separation of sample components, maximizing efficiency.



DissoPRO™ Software with 21 CFR Part 11 Compliance

- **Enhanced Data Security:** Full access controls, audit trails, electronic signatures, and ALCOA++ compliance.
- **User-Friendly Interface:** Simplified dissolution run protocols with secure login roles that meet current GMP/GLP standards.
- **Automatic Report Generation:** Receive a single, consolidated report upon dissolution completion, covering standard system suitability test, dissolution parameters and data analysis.



Compendial USP 1/2/5/6 Apparatus

- **Overhead Manifold:** Precisely controls the position of fiber optic probes and temperature sensors, reducing hydrodynamic effects for accurate results.
- 6 or 8 vessel dissolution testing system used for drug release evaluation of formulated drugs.
- **Low Evaporation Dissolution System:** Prevents media loss during extended dissolution testing and long-run studies.

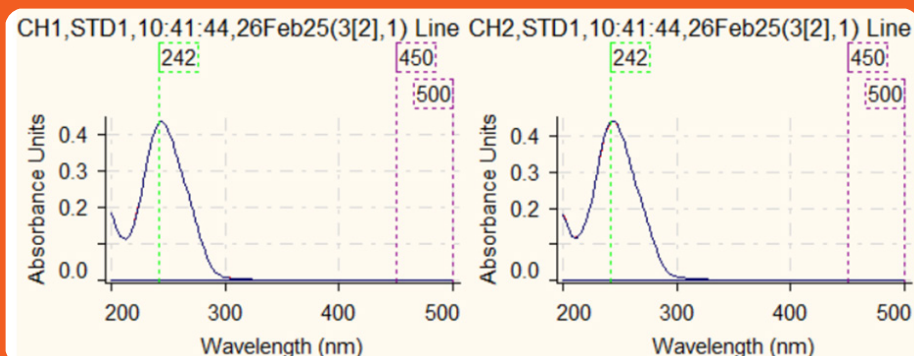


Figure 1.
UV-Vis spectra of prednisone.
Baseline correction algorithm is applied.

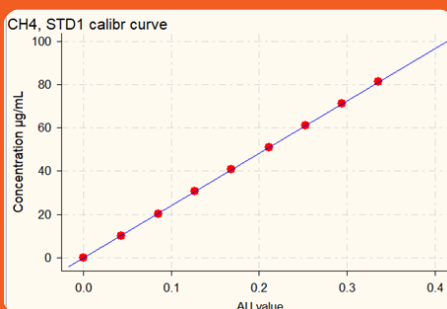
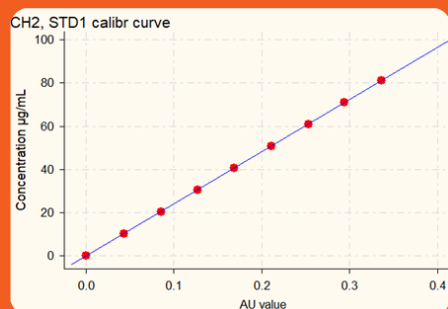
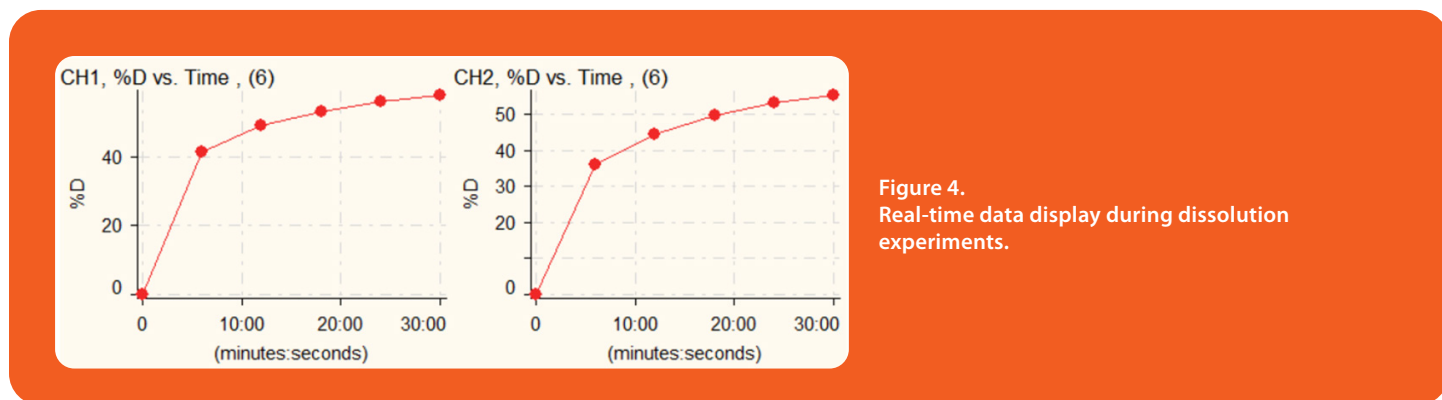


Figure 2.
Individual channel linearity checks
for working and control standards.

Channel 1		Channel 2	
Suitability		Suitability	
Test	Val	Test	Val
Norm	TRUE	Norm	TRUE
Type of Channel	Sample	Type of Channel	Sample
Integ	53 pass	Integ	57 pass
cAV	-1	cAV	-1
RSD A(1)	34.4829 pass	RSD A(1)	15.9330 pass
RSD A(2)	0.0535 pass	RSD A(2)	0.0594 pass
RSD B	0.1159 pass	RSD B	0.0479 pass
RSD C	N/A	RSD C	N/A
Std B Diff, %	0.0267 pass	Std B Diff, %	0.0540 pass
Std C Diff, %	N/A	Std C Diff, %	N/A
Intercept (mg/mL)	-0.0000 pass	Intercept (mg/mL)	-0.0000 pass
Slope	0.0231	Slope	0.0228
R2	1.0000 pass	R2	1.0000 pass
Standard Information 1		Standard Information 1	
Time / Conc[mg/mL]	AU	Time / Conc[mg/mL]	AU
26 Feb 2025 10:36:44 / 0.00000	0.001	26 Feb 2025 10:36:44 / 0.00000	0.001
26 Feb 2025 10:41:12 / 0.00000	0.434	26 Feb 2025 10:41:12 / 0.00000	0.440

Figure 3. Statistical data display including standard management acceptance criteria.



Time, Min	%D	Time, Min	%D	Time, Min	Vessel 1, °C	Vessel 2, °C	Bath, °C	Speed[rpm]
0.00	0.161	0.00	-0.203	0.00	36.9	37.0	36.9	N/A
6.00	37.040	6.00	35.092	6.00	37.0	37.1	37.0	50.0
12.00	45.139	12.00	43.224	12.00	37.1	37.1	36.9	50.0
18.00	49.874	18.00	48.283	18.00	37.1	37.1	37.0	50.0
24.00	53.038	24.00	51.801	24.00	37.1	37.1	37.0	50.0
30.00	55.192	30.00	54.355	30.00	37.1	37.1	37.0	50.0

Figure 5. Tabular analytical and dissolution data included in the experiment report.

Experience Pion's Expertise in Real-Time QC Dissolution

The Pion **DissoSpec** QC Dissolution Monitoring System provides a sophisticated, efficient solution for QC dissolution testing. Combining real-time, eco-friendly analysis with simplified, comprehensive reporting, **DissoSpec** offers consistent, compliant, and cost-effective

dissolution testing. Simplify your QC processes with **DissoSpec**, a solution designed to meet the demands of modern pharmaceutical analysis.



Why Choose **DissoSpec**?

Traditional Approach

Delayed results: Analytical work begins after the dissolution test concludes, prolonging the review process and creating bottlenecks in QC.

Complex, multi-step reporting: Data from dissolution, standard handling, and analytical analysis requires multiple reports, slowing down review and approval processes.

Increased analyst bias: Multi-user shifts introduce variability and potential bias into results, compromising data integrity.

High cost of consumables: Liquid chromatography (LC) requires solvents, consumables, and regular maintenance, impacting both time and environmental resources.

Pion **DissoSpec** Approach

Real-time data: Data is available mid-test, enabling rapid, proactive decisions and accelerating QC time lines for faster product release.

Single unified report: **DissoSpec** delivers one comprehensive report covering dissolution, standards, and analytics data, ready for immediate review and audit.

Automated, consistent testing: Real-time *in situ* measurements reduce user bias and ensure data consistency across shifts, preserving data integrity.

Eco-friendly UV-vis: No consumables needed; **DissoSpec** reduces waste, solvent use, and maintenance, providing a cost-effective, environmentally conscious solution.

Technical Specifications

Rainbow R6 UV-Vis Module

Channels: **Options of 6 or 8**

Lamp Source: **Deuterium**

Path Lengths: **1, 2, 5, 10, 20 mm**

Power: **200 W**

Dimensions: **18H x 16W x 44D cm**

Voltage: **120 or 240V**

Operating System: **Windows 10/11 Pro, 64-bit**

Dissolution Bath

Drive/Vessel Positions: **8**

Temperature Range: **25-45° C**

Stirring Speed: **25-250 rpm**

Power: **1000 W**

Dimensions: **88H x 61W x 56D cm**

Voltage: **120 or 240 V**