Rainbow R6 Concentration Monitor

An *in vitro* analytical platform for dissolution and flux measurements of whole dose formulations using biorelevant volumes.

The Rainbow R6 Concentration Monitor is an *in-situ* Fiber Optic UV-VIS spectrometer with a Deuterium lamp light source and photodiode array detection. It is a powerful analytical instrument that correctly and accurately measures dissolution in real-time.

Equipped with up to 8 independent fiber-optic channels the Rainbow R6 provides high accuracy and repeatability in concentration measurements.

- No delays between sample draw and analysis – the Rainbow R6 provides concentration measurement in real-time.
- Provides rich data for very short sampling intervals needed for immediate release formulations – sample measurement can be obtained in less than 5 seconds in an 8-vessel dissolution tester.
- Unattended, extended assays are possible as concentration measurement is made directly in assay media.

The Rainbow R6 Concentration Monitor is used for early-phase compound screening, pre-formulation and formulation studies, and quality control.

- Dissolution profiles and absorption prediction studies with limited or high potency API or biorelevant volumes
- Analytical R&D and QC for compendial dissolution testing when used with Pion's DissoPRO software
- FLUX systems help simultaneously determine the effect of formulation on dissolution, solubility and permeability of API.

Product Configurations

- The **MicroDISS** system consists of an R6 and a low-volume dissolution bath for dissolution monitoring where only small quantities of API are available. It allows testing in media volumes as low as 2 mL to 20 mL.
- The **MiniDISS** system consists of an R6 and a miniDT small volume tester for biorelevant dissolution testing and is available with100, 200 and 250 mL vessels.
- The **MicroFLUX** system consists of an R6 and a low-volume mini-bath with the addition of low-volume FLUX vessels requiring only 20 mL of media for FLUX experiments where only small sample amounts are available.
- The **MacroFLUX** system consists of an R6 coupled with a compendial dissolution apparatus and submerging Flux acceptor chambers. The macroFLUX technology is compatible with various Compendial dissolution baths available in the market.
- The **BioFLUX** system consists of an R6 coupled with a compendial dissolution apparatus with 500 mL vessel and submerging Flux acceptor chambers allowing biorelevant volumes on the donor side.
- The **miniFlux** system consists of the R6 coupled with the miniDT 250 mL volume dissolution bath and a submerging acceptor chamber. The miniFlux system allows to run flux assays with various biorelevant volumes including 250 mL and 130 mL on the donor side.
- The **Scissor N3 (or N6)** is compatible for use with Rainbow R6 for *in-situ* concentration monitoring with the Scissor subcutaneous injection site simulator.

	MicroDISS	MiniDISS	MicroFLUX	MacroFLUX	BioFLUX	MiniFLUX
VOLUME OF VESSELS	12 mm and 24 mm diameter vials	100, 150, 200 and 250 mL	24 mm diameter vials	1000 mL	500 mL	250 mL and 200 mL
MINIMUM MEDIA VOLUME, TYPICAL	2 mL (12 mm vial 5 mL (24 mm vial)	40 mL for 100 mL vessel 100 mL for 250 mL vessel	16 mL (24 mm vial)	800 mL	200 mL	120 mL for 200 mL vessel 170 mL for 250 mL vessel

REQUIRED ACCESSORIES:

- PC or laptop with Windows 10 or 11, 64-bit operating system and minimum 2.3 GHz microprocessor, 8 GB RAM, 10 GB of free disk space (500 GB or higher storage recommended), one free USB port, and Microsoft Excel for data export
- AuPRO Version 7 data acquisition and processing software
- Windows "Memory Integrity" disabled (usually disabled by default as it interferes with many device drivers)

TECHNICAL SPECIFICATIONS:

Light Source: Deuterium

- Optimal wavelength range of Deuterium lamp: 240-500 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

OPTIONAL ACCESSORIES:

- The IDR press accessory is used with MicroDISS applications. It compresses powder to produce tablets of consistent surface to deliver replicable results for intrinsic dissolution measurements.
- Vessel covers are available with ports for fiber optic probe insertion for FLUX applications
- Baths and heater circulators are available for all Pion Dissolution Testers
- Standardization stations are used to collect blank (100% transmittance) and standard spectra. They are available for straight dip probes, J-probes and MacroFLUX probes.

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 additional tips of 1- and 20-mm path length.
- J-probes which use the same interchangeable probe tips.
- Fixed path length angled probes used primarily for MacroFLUX.
- Scissor Fiber Optics Probe which is a fixed path length straight probe used for analysis in the Scissor N3.

	Height	Width	Depth
Rainbow R6 alone	275mm (10.9 inches)	177mm (7 inches)	436mm (17.2 inches)
MicroDISS/ MicroFLUX (side-by-side) configuration	635mm (25 inches)	609.6mm (24 inches)	431.8mm (17 inches)
miniDISS and miniFlux (Side-by-side) configuration	870mm (34.3 inches)	1250mm (49.2 inches)	610mm (24 inches)
MacroFLUX and BioFLUX (Estimated as size is dependent on compendial dissolution apparatus employed	1005mm (39.6 inches)	947mm (37.3 inches)	620mm (24.4 inches)

Pion

Pion stands behind the science

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Specifications subject to change without notice
Product sheet 90-40001