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DISSOLUTION AUTOSAMPLER

Dissolution Tester with Autosampler (8-Vessel)

Dissolution autosampler couples an eight-vessel intelligent dissolution tester with an integrated automatic sampling module, delivering hands-off pharmacopoeial dissolution testing for pharmaceutical QC labs, generic drug developers, and stability testing groups. The platform runs USP Apparatus 1 (basket) and Apparatus 2 (paddle) methods, then withdraws, filters, and dispenses each aliquot into positioned collection vials without operator involvement. Torontech configured the eight-channel setup for labs running a standard USP six-vessel batch with two spare stations for method verification or duplicate runs.

Independent temperature control on every vessel, magnetic-pump sampling, and modular tubing sets support the throughput demands of a busy pharmaceutical QC workstation. A single interface handles method setup, sampling schedules, cleaning cycles, and audit trail logging, and USB export moves raw data straight to lab PCs or LIMS. The system meets international pharmacopoeia requirements and holds CE certification for the EU market.

Torontech supplies the dissolution autosampler with IQ/OQ qualification documentation for GMP validation, three-tier operator access rights for audit accountability, and a modular sampling head design that reduces maintenance downtime between batches. Labs replace peristaltic pump lines and repetitive manual pipetting steps with a validated, self-cleaning automated workflow.

APPLICATIONS

Dissolution Autosampler - ToronDISS™ A8 Applications

The dissolution autosampler serves pharmaceutical QC, formulation, and contract testing workflows where dissolution profile accuracy and traceability matter.

- Solid Oral Dosage Release Testing: routine batch-release dissolution analysis of tablets, capsules, and coated dosage forms per USP <711> paddle and basket methods
- Generic Drug Development: comparative dissolution profiling against reference-listed drug products for ANDA submissions and f2 similarity factor calculations
- Formulation Screening: parameter studies across dissolution media, apparatus, and rotation speed during early-stage development of oral dosage forms
- Extended-Release Product Analysis: unattended multi-point sampling over 12 to 24 hour dissolution profiles for controlled-release and delayed-release products
- Stability Program Testing: dissolution performance monitoring under ICH storage conditions to support shelf-life determination and expiry date extensions
- Bioequivalence Studies: multi-media dissolution profile generation in support of biowaiver applications and BCS-classification workflows
- Contract Testing Laboratories: audit-trail-backed dissolution analysis for CRO and CDMO clients requiring full documentation packages
- Pharmacopoeial Compliance Verification: method transfer and verification runs for facilities aligning existing products to USP or Ph.Eur. dissolution monographs


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Standards

The dissolution autosampler is designed to align with internationally recognized pharmacopoeia dissolution methods and carries CE certification for the EU market.

- USP <711> - Dissolution Test for Pharmaceutical Dosage Forms
- Ph.Eur. 2.9.3 - Dissolution Test for Solid Dosage Forms
- EN ISO 12100:2010 - Safety of Machinery: General Principles for Design, Risk Assessment and Risk Reduction
- EN 60204-1:2018 - Safety of Machinery: Electrical Equipment of Machines
- EN 61010-1:2010+A1:2019 - Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
- EN IEC 61326-1:2021 - Electrical Equipment for Measurement, Control, and Laboratory Use: EMC Requirements

CE certification covers the EU Machinery Directive 2006/42/EC and EMC Directive 2014/30/EU. IQ/OQ qualification documentation is available upon request.

FEATURES

Dissolution Autosampler - ToronDISS™ A8 Key Features

The dissolution autosampler integrates a validated eight-vessel dissolution bath with an autosampling circuit in a single platform, replacing manual pipetting and vial transfer steps with a validated automated workflow.

- Eight-Vessel Dissolution Bath: handles a standard USP six-vessel run with two spare stations available for method verification, duplicate testing, or reference standard runs
- Three-Tier User Access Control: administrator, method developer, and operator roles with individually logged actions meet GMP audit trail requirements and support 21 CFR Part 11-ready workflows

- Independent Cell Temperature Control: each of the eight vessels carries its own temperature probe and dual-layer thermal barrier, holding bath uniformity to 0.1°C and accuracy to ±0.3°C
- Scheduled Preheat Function: media reaches setpoint before staff arrive, letting the lab begin testing at shift start rather than waiting on bath warm-up
- Magnetic Pump Sampling Circuit: pulsation-free withdrawal maintains sample integrity through the tubing and inline filter, producing cleaner UV absorbance data than peristaltic pump alternatives
- Isolated Sampling and Tray Fluid Paths: separate lines for withdrawal and dispensing eliminate cross-contamination between vessels and between sampling time points
- Automatic Pipeline Cleaning: sampling heads and lines self-flush between intervals to remove residue and prevent carryover across the dissolution profile
- Modular Component Design: sampling heads, tubing sets, and filter cartridges swap out in seconds without tools, reducing maintenance downtime between batches
- 180-Vial Sample Storage: onboard tray holds a complete multi-point profile for extended-release products without operator refilling during unattended overnight runs
- Manual and Automatic Dosing Modes: supports both operator-driven tablet drop and automated drug addition heads for method development and validated QC procedures
- Stored Method Library: frequently used dissolution methods and sampling schedules save to the controller for one-touch recall on repeat batches
- Direct USB Data Export: raw dissolution and sampling records transfer to lab PCs or LIMS without proprietary drivers or manual transcription

THEORY & METHOD

Theory and Method

Dissolution testing quantifies the rate at which a solid dosage form releases its active pharmaceutical ingredient into a defined medium under controlled hydrodynamic conditions. USP <711> defines Apparatus 1 (basket) and Apparatus 2 (paddle) as the reference methods, both of which generate reproducible fluid shear at the tablet or capsule surface through calibrated shaft rotation. Concentration measurements taken at defined time points build the dissolution profile that regulators use to predict in vivo drug release.

Result accuracy depends on tight control of media temperature, rotation speed, shaft geometry, and sampling timing across every vessel. The dissolution autosampler holds temperature uniformity to 0.1°C and accuracy to ±0.3°C through independent probes on each of the eight vessels with a dual-layer thermal barrier. A synchronous drive maintains rotation stability within 1% from 10 to 300 RPM, satisfying the ±0.5 RPM tolerance in USP <711>. Swing radius stays under 0.5 mm and axial deviation under 1.0 mm.

Automated sampling then draws aliquots through a magnetic pump architecture that generates pulsation-free flow, feeding each vessel through its own dedicated tubing and filter line to prevent cross-contamination. Between sampling intervals, the pipeline self-flushes to remove residue and eliminate carryover. Sampling volume, interval schedule, and return volume are programmed at method setup and executed autonomously across the run.

TECHNICAL SPECIFICATIONS

Dissolution Autosampler - ToronDISS™ A8 Technical Specifications

Dissolution Parameters

Parameter	Specification
Vessels	8 channels
Swing Radius Consistency	≤ 0.5 mm

Parameter	Specification
Rotation Speed Consistency	≤ 1.0 mm
Rotation and Axis Deviation	≤ 1.0 mm
Speed Range	10 to 300 RPM
Rotation Speed Stability	≤ 1%
Temperature Adjustment Range	Ambient to 45.0°C
Temperature Uniformity	0.1°C
Temperature Accuracy	±0.3°C
Voltage	AC 220 V ±10%, 50 Hz (110V is also available)

Sampling System Parameters

Parameter	Specification
Sampling Channels	8 channels
Sampling Cycle Time	≤ 15 seconds
Sampling Time Precision	≤ 999.9 h / 59 min 59 s
Sampling Volume	< 10 mL
Return Volume	< 1% (tube length within 10 mL standard)
Sampling Interval	First interval 2 to 5 minutes; subsequent intervals user-defined
Sample Storage Capacity	180 vials
Voltage	AC 220 V ±10%, 50 Hz (110V is also available)

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