TORONTECH

AUTOMATIC 8-VESSEL DISSOLUTION TESTER

Automatic 8-Vessel Dissolution Tester - ToronDISS™ 8I

ToronDISS™ 8I Automatic 8-Vessel dissolution tester delivers pharmacopoeial dissolution testing with full GMP audit trails for pharmaceutical QC labs, generic drug developers, and R&D groups working with low-dose formulations. The instrument runs USP Apparatus 1 (basket) and Apparatus 2 (paddle) methods across eight vessels, and supports an optional mini-paddle accessory set for small volume dissolution testing of potent APIs and low-dose dosage forms. Torontech built the platform around three-tier access control, timestamped operator logging, and automatic drug addition for reproducible results.

Real-time bath temperature control with dual-layer thermal protection holds uniformity to 0.1°C and accuracy to ±0.3°C, satisfying the ±0.5°C tolerance in USP <711>. A synchronous drive maintains rotation stability within 1% across the 10 to 300 RPM range. Onboard storage saves frequently used dissolution methods and sampling solutions, letting operators recall validated setups with one action rather than re-programming for every batch.

Torontech supplies the ToronDISS™ 8I with IQ/OQ qualification documentation for GMP validation and CE certification for the EU market. The mini-paddle accessory upgrade adapts the same base bath to USP small volume dissolution testing, letting labs support both standard-dose and low-dose product lines from a single workstation.

APPLICATIONS

Automatic 8-Vessel Dissolution Tester - ToronDISS™ 8I Applications

The ToronDISS™ 8I supports dissolution testing across pharmaceutical QC, R&D, and contract analysis workflows, with dedicated capability for low-dose and small volume methods.

- Routine Batch Release Testing: dissolution QC of tablets, capsules, and coated dosage forms per USP <711> paddle and basket methods with full audit trail documentation

- Low-Dose Drug Product Testing: mini-paddle accessory enables small volume dissolution testing of high-potency APIs where standard 900 mL vessels dilute drug concentration below detection limits
- Formulation Development: comparative dissolution profiling of prototype formulations to guide excipient selection and process design for both standard and low-dose products
- Generic Drug Development: multi-media dissolution profile generation for ANDA submissions requiring f2 similarity factor calculations
- Stability Program Testing: dissolution performance monitoring under ICH storage conditions to support shelf-life determination
- Method Development and Validation: parameter screening across pH media, apparatus, and rotation speed combinations to establish discriminating dissolution methods
- Contract Testing Laboratories: audit-trail-backed dissolution analysis for CRO and CDMO clients requiring full documentation packages
- Biopharmaceutical and Orphan Drug R&D: small volume dissolution of limited API supply where sample conservation matters


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ToronDISS™ 8I
Automated 8-Vessel Dissolution Tester
USB

Standards

The ToronDISS™ 8I 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

Automatic 8-Vessel Dissolution Tester - ToronDISS™ 8I Key Features

The ToronDISS™ 8I combines eight dissolution cells with three-tier user access, automatic drug addition, and an optional mini-paddle upgrade, delivering pharmacopoeial testing capability for both standard and low-dose formulations.

- Eight-Vessel Dissolution Bath: matches the standard USP six-vessel protocol with two spare stations for method verification, duplicate testing, or reference standard runs
- Optional Mini-Paddle Accessory Kit: adapts the bath to small volume dissolution testing for low-dose drug products and potent APIs where standard 900 mL vessels dilute below detection limits

- 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
- Timestamped Audit Trails: every parameter change and operator action logs with user ID and timestamp for full documentation traceability under GMP inspection
- Real-Time Dual-Layer Temperature Control: continuous bath regulation with a dual-layer thermal barrier holds uniformity to 0.1°C and accuracy to ±0.3°C throughout the run
- Scheduled Preheat Function: media reaches setpoint before staff arrive, letting the lab begin testing immediately at shift start rather than waiting on bath warm-up
- Manual and Automatic Drug Addition: supports both operator-driven tablet drop and automated dosing heads for simultaneous drop across all eight vessels, eliminating stagger-time variance
- Vapor Condensation Design: minimizes evaporation loss across extended-release dissolution profiles, preserving media volume and concentration accuracy over 12 to 24 hour runs
- Quick-Release Pipeline Connectors: tool-free reconfiguration of the circulation network shortens setup time between methods and speeds routine maintenance
- Stored Method Library: frequently used dissolution methods and sampling solution records save to the controller for one-touch recall on repeat batches
- Direct USB Data Export: raw dissolution records transfer to lab PCs or LIMS without proprietary drivers or manual transcription
- IQ/OQ Qualification Package: factory-supplied installation and operational qualification documentation supports GMP validation on delivery

THEORY & METHOD

Theory and Method

Dissolution testing measures 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 at defined time points build the dissolution profile that predicts in vivo drug release behavior.

Reproducibility depends on tight control of media temperature, rotation speed, shaft geometry, and sampling timing. The ToronDISS™ 8I holds bath temperature uniformity to 0.1°C and accuracy to ±0.3°C through real-time regulation with a dual-layer thermal barrier that isolates the sample environment from ambient fluctuations. 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.

The optional mini-paddle accessory adapts the paddle geometry and vessel size for small volume dissolution testing, typically 100 to 250 mL media, addressing the analytical challenge of low-dose or high-potency drug products. Standard 900 mL vessels dilute low-dose APIs below UV detection thresholds, whereas mini-paddle configurations preserve concentration for accurate measurement while retaining the hydrodynamic reproducibility of USP Apparatus 2.

TECHNICAL SPECIFICATIONS

Automatic 8-Vessel Dissolution Tester - ToronDISS™ 8I Technical Specifications

Parameter	Specification
Vessels	8 channels
Swing Radius Consistency	≤ 0.5 mm
Rotation Speed Deviation	≤ 1.0 mm

Parameter	Specification
Axial 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 Control Precision	±0.3°C
Sampling Volume	< 100 mL
Sampling Time Capacity	≤ 999.9 h / 59 min 59 s
Optional Accessory	Mini-paddle kit for small volume dissolution
Voltage	AC 220 V ±10%, 50 Hz (110V is also available)

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