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6-VESSEL DISSOLUTION TESTER

6-Vessel Dissolution Tester - ToronDISS™ 6I

ToronDISS™ 6I 6-vessel dissolution tester matches the standard USP six-vessel testing protocol in a compact benchtop workstation built for pharmaceutical QC labs, R&D groups, and academic research programs. The instrument runs USP Apparatus 1 (basket) and Apparatus 2 (paddle) methods across six independently controlled cells, and adapts to specialized small volume dissolution work through optional 150 mL vessels and mini-paddle accessories. Torontech built the platform around three-tier access control, timestamped operator logging, and automatic drug addition to deliver GMP-grade traceability at a compact footprint.

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™ 6I with IQ/OQ qualification documentation for GMP validation and CE certification for the EU market. The combination of standard 900 mL and optional 150 mL vessel formats, paired with mini-paddle accessories, lets the same base bath handle both routine batch-release work and low-dose or high-potency drug product testing without a second instrument.

APPLICATIONS

6-Vessel Dissolution Tester - ToronDISS™ 6I Applications

The ToronDISS™ 6I supports dissolution testing across pharmaceutical QC, R&D, and small-volume analytical workflows, with dedicated capability for low-dose and specialized methods.

- Routine USP Six-Vessel Batch Release: 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: 150 mL vessels and mini-paddle configuration enable dissolution of high-potency APIs where standard 900 mL vessels dilute drug concentration below detection limits
- High-Potency API Formulations: small volume dissolution reduces media consumption and simplifies waste handling for cytotoxic, hormonal, and controlled-substance products
- Formulation Development: comparative dissolution profiling of prototype formulations to guide excipient selection and manufacturing process design
- Generic Drug Development: dissolution profile generation for ANDA submissions requiring f2 similarity factor calculations against reference-listed drug products
- Stability Program Testing: dissolution performance monitoring under ICH storage conditions to support shelf-life determination and expiry date extensions
- Biopharmaceutical and Orphan Drug R&D: dissolution studies where limited API supply favors small volume testing that conserves sample material
- Academic Pharmaceutical Research: teaching and research labs requiring pharmacopoeial method capability at a workstation footprint suited to shared laboratory space


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ToronDISS™ 6I
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Standards

The ToronDISS™ 6I 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

6-Vessel Dissolution Tester - ToronDISS™ 6I Key Features

The ToronDISS™ 6I combines six dissolution cells with three-tier user access, automatic drug addition, and dedicated small volume configuration options in a compact pharmacopoeial workstation.

- Six-Vessel Bath Matching USP Protocol: runs the standard USP six-vessel dissolution test in one instrument with no wasted capacity or unused cells
- Optional 150 mL Small Volume Vessels: dedicated small vessel format enables dissolution testing of low-dose and high-potency drug products at concentrations measurable by standard UV spectrophotometry

- Optional Mini-Paddle Accessory Kit: matched paddle geometry preserves USP Apparatus 2 hydrodynamics when running small volume methods
- 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 and Sampling: supports both operator-driven tablet drop and automated dosing across all six vessels, eliminating stagger-time variance in method start
- Quick-Release Circulation Pipeline: professional-grade tool-free connectors on the circulation network shorten setup time between methods and speed 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.

Reproducibility depends on tight control of media temperature, rotation speed, shaft geometry, and sampling timing. The ToronDISS™ 6I 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.

Small volume dissolution testing addresses a specific analytical challenge with low-dose drug products. When an API is dosed at a few milligrams, its concentration in a standard 900 mL vessel falls below the linear detection range of most UV spectrophotometers. Reducing the media volume to 150 mL preserves measurable concentration while retaining the hydrodynamic behavior of USP Apparatus 2 through matched mini-paddle geometry. This lets low-dose products meet the same pharmacopoeial reproducibility criteria as standard-dose formulations.

TECHNICAL SPECIFICATIONS

6-Vessel Dissolution Tester - ToronDISS™ 6I Technical Specifications

Parameter	Specification
Vessels	6 channels
Swing Radius Consistency	≤ 0.5 mm
Rotation Speed Deviation	≤ 1.0 mm
Axial Deviation	≤ 1.0 mm

Parameter	Specification
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 Small Volume Vessels	2 × 150 mL
Optional Accessory	Mini-paddle kit for small volume dissolution
Voltage	AC 220 V ±10%, 50 Hz (110V is also available)

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