



SINGLE-VESSEL DISSOLUTION TESTER

Single-Vessel Dissolution Tester - ToronDISS™ 1

ToronDISS™ 1 single-vessel dissolution tester delivers pharmacopoeial dissolution testing capability in a compact benchtop workstation built for formulation development, method screening, and academic pharmaceutical research. The instrument runs USP Apparatus 1 (basket) and Apparatus 2 (paddle) methods on one dissolution cell, letting scientists explore formulation and media parameters without tying up a multi-vessel bath used for batch-release QC work. Torontech built the platform around a touchscreen interface, automated cup and paddle centering, and audit trail logging for GMP-grade traceability at R&D scale.

Real-time bath temperature control with dual-layer thermal protection and onboard calibration holds uniformity to 0.1°C and accuracy to $\pm 0.3^{\circ}\text{C}$, satisfying the $\pm 0.5^{\circ}\text{C}$ tolerance in USP <711>. A synchronous drive maintains rotation stability within 1% across the 10 to 300 RPM range. USB data export moves raw dissolution records straight to lab PCs for downstream analysis and report generation, and the modular sampling head swaps in seconds during method changeovers.

Torontech supplies the ToronDISS™ 1 with IQ/OQ qualification documentation for GMP validation and CE certification for the EU market. The automated centering system aligns paddle and vessel geometry at each run, addressing the largest single source of manual apparatus qualification error in USP <711> dissolution testing.

APPLICATIONS

Single-Vessel Dissolution Tester - ToronDISS™ 1 Applications

The ToronDISS™ 1 supports pharmaceutical development and educational workflows where a single dissolution cell fits the study design better than a full multi-vessel bath.

- Dissolution Method Development: exploratory testing across pH media, apparatus, and rotation speed combinations during early method design before scaling to a six-vessel bath for validation
- Formulation Screening: single-vessel comparative testing of prototype excipient blends and manufacturing process variables during early formulation R&D
- Discriminating Method Design: parameter screening to identify test conditions that distinguish acceptable from failing product lots for later stability and change-control work
- Preclinical Dissolution Studies: dissolution profiling of investigational drug candidates where API supply is limited and full six-vessel testing would consume excessive material
- Academic Pharmaceutical Research: teaching and research labs requiring pharmacopoeial method capability at a workstation footprint suited to shared laboratory space
- Compounding Pharmacy Quality Checks: dissolution verification of small-batch compounded preparations that do not require six-vessel batch release protocols
- Apparatus Qualification and Calibration: reference standard testing and periodic verification of paddle geometry, rotation speed, and temperature performance against USP calibration criteria
- Troubleshooting and Root Cause Investigation: single-vessel replay of failing dissolution results to isolate variables during OOS investigations without occupying the batch-release bath



Standards

The ToronDISS™ 1 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

Single-Vessel Dissolution Tester - ToronDISS™ 1 Key Features

The ToronDISS™ 1 combines a single dissolution cell with automated apparatus centering and touchscreen operation, delivering pharmacopoeial method capability in a compact R&D workstation.

- Automated Cup and Paddle Centering: motorized geometry alignment at each run holds swing radius and shaft position within USP apparatus qualification tolerance, removing the largest source of manual setup error
- Touchscreen Human-Machine Interface: full-color touchscreen navigation for method setup, run control, and result review, replacing multi-button controllers and paper method sheets

- Real-Time Temperature Control with Calibration: continuous bath regulation with a dual-layer thermal barrier and onboard calibration function holds uniformity to 0.1°C and accuracy to $\pm 0.3^\circ\text{C}$
- Independent Temperature Regulation: dedicated temperature control loop for the single cell delivers stability across long-duration extended-release profiles up to 9,999 minutes
- Modular Sampling System: sampling head, tubing, and filter cartridge swap in seconds without tools, cutting maintenance downtime between method changeovers
- USB Data Export and Report Generation: raw dissolution records transfer to lab PCs for downstream analysis, with report templates supporting method development documentation
- Compact Benchtop Footprint: single-cell format fits shared bench space in R&D labs, teaching facilities, and small QC departments where a multi-vessel bath is oversized
- Multi-Language Interface: interface language selection supports laboratories operating in multiple regional languages
- 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.

Single-vessel testing addresses a specific role in the pharmaceutical development lifecycle. Batch-release testing under USP <711> requires six vessels to satisfy the stage-1, stage-2, and stage-3 acceptance criteria on dosage-form uniformity, so a single-vessel instrument is not intended for lot-release decisions. Instead, single-vessel testers fit the exploratory work that

precedes validated methods: parameter screening, formulation comparisons, and calibration verification, where running one cell at a time gives faster turnaround and lower media consumption.

Paddle alignment inside the vessel is the largest source of variability in manual dissolution setups. USP <711> apparatus suitability testing requires the paddle to sit centered along the vessel axis with a defined bottom clearance, and small deviations shift the hydrodynamic profile enough to alter dissolution results. The ToronDISS™ 1 automates this centering step at each run, delivering geometry within apparatus qualification tolerance without operator-to-operator variability.

TECHNICAL SPECIFICATIONS

Single-Vessel Dissolution Tester - ToronDISS™ 1 Technical Specifications

Parameter	Specification
Vessels	1 channel
Swing Radius Consistency	≤ 0.5 mm
Rotation Speed Deviation	≤ 1.0 mm
Axial Deviation	≤ 2.0 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 Cycle Time	≤ 15 seconds

Parameter	Specification
Sampling Time Capacity	≤ 9,999 minutes
Voltage	AC 220 V ±10%, 50 Hz (110V is also available)



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