TORONTECH

12-VESSEL DISSOLUTION TESTER

12-Vessel Dissolution Tester - ToronDISS™ 12

ToronDISS™ 12 12-vessel dissolution tester delivers high-throughput pharmacopoeial dissolution testing for pharmaceutical QC labs, formulation development teams, and contract testing organizations running multiple products in parallel. The instrument runs USP Apparatus 1 (basket) and Apparatus 2 (paddle) methods across twelve independently controlled vessels, letting labs process two complete USP six-vessel batches concurrently or dedicate the full bank to a single high-volume formulation. Torontech built the platform around independent per-cell temperature regulation, a sampling manifold, and a data management stack aligned with GMP audit requirements.

Real-time temperature control on each of the twelve vessels holds bath 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 data storage, three-tier user access, and USB export produce the traceability documentation regulators expect from routine batch-release testing.

Torontech supplies the ToronDISS™ 12 with IQ/OQ qualification documentation for GMP validation and CE certification for the EU market. The system is compatible with an optional automatic sampling module for labs that plan to automate their dissolution workflow later, protecting the equipment investment as testing volumes grow.

APPLICATIONS

12-Vessel Dissolution Tester - ToronDISS™ 12 Applications

The ToronDISS™ 12 supports high-throughput dissolution testing across pharmaceutical QC, R&D, and contract analysis workflows.

- High-Volume Batch Release Testing: routine dissolution QC across multiple product batches per day using USP <711> paddle and basket methods
- Parallel Multi-Product Testing: two independent USP six-vessel runs on separate formulations simultaneously, reducing instrument scheduling conflicts in busy QC labs
- Formulation Development: comparative dissolution profiling of prototype formulations to guide excipient selection, process optimization, and dosage form design
- Generic Drug Development: multi-media 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
- Bioequivalence and Biowaiver Studies: multi-condition dissolution profiles for BCS-classification workflows and biowaiver applications
- Contract Testing Laboratories: audit-trail-backed dissolution analysis for CRO and CDMO clients requiring full documentation packages
- Method Development and Validation: parameter screening across pH media, apparatus, and rotation speed combinations to establish discriminating dissolution methods

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Standards

The ToronDISS™ 12 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

12-Vessel Dissolution Tester - ToronDISS™ 12 Key Features

The ToronDISS™ 12 combines twelve independently controlled dissolution cells with an integrated sampling manifold, delivering high-throughput pharmacopoeial testing in a single workstation.

- Twelve-Vessel Parallel Testing: runs two full USP six-vessel batches concurrently on separate formulations, doubling daily throughput without a second instrument
- 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 Regulation: each of the twelve vessels carries its own temperature probe with a 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 immediately at shift start rather than waiting on bath warm-up
- Isolated Sampling and Tray Fluid Paths: separate lines for sample withdrawal and dispensing eliminate cross-contamination between vessels and between time points
- 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 sampling network shortens setup time between methods and speeds routine maintenance
- Modular Sampling Components: replaceable sampling heads, tubing sets, and filter cartridges swap in seconds, reducing maintenance downtime between batches
- Manual and Automatic Dosing Modes: supports both operator-driven tablet drop and automated drug addition heads for method development and validated QC procedures
- Autosampler Upgrade Path: compatible with an optional automatic sampling module for labs planning to fully automate their dissolution workflow later
- 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 records transfer to lab PCs or LIMS without proprietary drivers or manual transcription

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 at a fixed depth. Concentration measurements at defined time points build the dissolution profile that predicts in vivo drug release behavior.

Reproducibility across vessels depends on tight control of media temperature, rotation speed, shaft geometry, and sampling timing. The ToronDISS™ 12 holds temperature uniformity to 0.1°C and accuracy to ±0.3°C through independent probes on each of the twelve cells 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.

The dissolution manifold supports both manual sampling through positioned ports and automated integration when paired with an optional autosampling module. Separate sampling and tray lines prevent cross-contamination between vessels, and a vapor condensation design minimizes evaporation loss across long-duration extended-release profiles. Quick-release connectors on the circulation pipeline let operators reconfigure the sampling network without tools between method setups.

TECHNICAL SPECIFICATIONS

12-Vessel Dissolution Tester - ToronDISS™ 12 Technical Specifications

Parameter	Specification
Vessels	12 channels
Swing Radius Accuracy	≤ 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
Voltage	AC 220 V ±10%, 50 Hz (110V is also available)

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