

BETTER FUNCTIONALITY | BETTER PRECISION | BETTER ANALYSIS



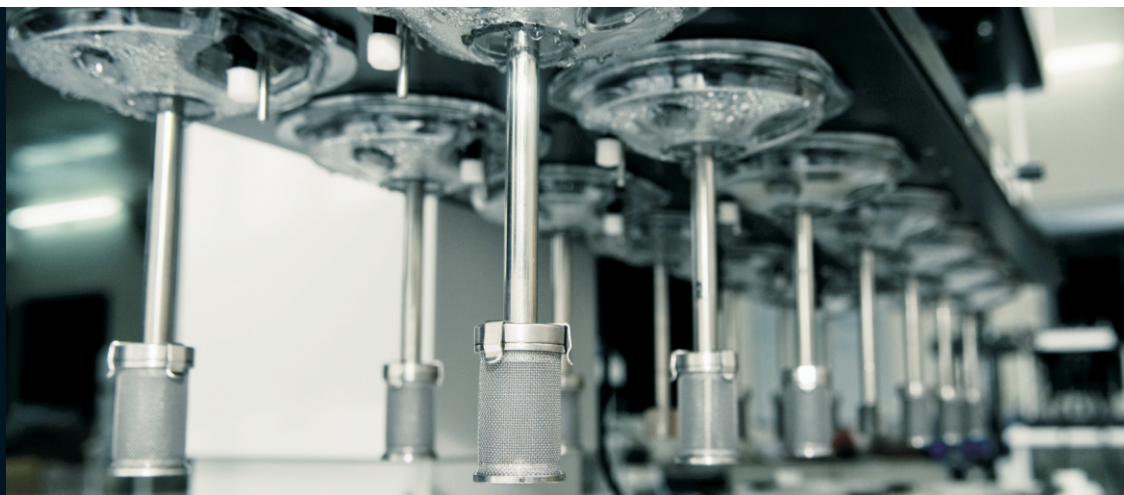
## Tablet Dissolution Test Apparatus DS 14000 (Basic)

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## DISSOLUTION TEST APPARATUS

Dissolution Tests are conducted to determine the drug release patterns, physiological availability and bioavailability of formulated drug products. It is also used as a quality control tool. The Dissolution rate of a drug from the solid state is defined as the amount of drug substance that goes into solution per unit time under standardised conditions of liquid / solid inter face, temperature, and solvent composition.

LABINDIA brings to you the State-of-the-art Dissolution Testing Apparatus in elegant design with advanced features, which support USP 1, 2, 5 & 6. Apparatus for Intrinsic test & stationary basket methods are available.



## STANDARD FEATURES

- **Advanced, Micro-Controller based:** User-friendly, complies with current USP, IP & EP specifications.
- **Splash waterproof keyboard:** Alphanumeric polyester soft keys for keyboard.
- **Moulded water bath** with **12+2 (6+1 & 6+1)** vessel configuration enables comparative studies.
- **External vibration free Water Circulator:** for uniform water circulation, with audible, low water level alarm, with indication on display for safety.
- **Mono shaft design** with automatic adjustment for 25 mm depth setting with easy changeover between Apparatus I & II eliminates routine height validation as per USP.
- **Paddles, Baskets and Vessels** are laser mark with serial numbers for traceability.
- **Tablet dispenser** - drops 12 dosage form at single instant. (Optional)
- **Low Evaporation Lids:**
  - » The conical shape low evaporation recovery lids reduces media loss during long run.
  - » Integrated pre-centered lids; no manual removal or positioning of lids. This ensures automatic vessel centering and precise positioning of paddle/basket with shaft without any special tool as per pharmacopeia requirements.
- **State-of-the-art design:**
  - » Easy placement and locking of vessels, the Ease-align system allows the vessels to simply slide into the place (Bionet Locking). Once placed, vessels do not float even when empty.
  - » Facility to monitor Vessel temp., with DTS Technology (Digital Temperature Sensor)

## SOFTWARE

- **GLP Compliance:**
  - » Alphanumeric entries of Sample Name, Sample Number and Identification Number for authentication.
  - » Built-in Real Time Clock (RTC) for date and time on display and on printout.
  - » Daily Auto Incremented Run Number and factory entered CUSTOMER NAME with Instrument Serial Number on report printouts make the system foolproof.
  - » Non-Volatile memory storage of 15 methods with parameters.
- **Protects Editing, Avoids invalid entries:**
  - » Two tier password protection - Admin and User
- **Ease in operation:**
  - » Dissolution RUN can be started with last run parameters.
  - » Facility to view Set Parameters during RUN.
  - » Auto Start facility to continue the dissolution analysis in case of short power interruption (especially useful for long duration analysis of sustained release tablets).
  - » Reports can be obtained even after Resetting / Power off / Power failure conditions.
  - » Error indication helps user to trace the problem.
- **Alarms and Indications:**
  - Audible indication for ready state of instrument.
- **Wake-up Alarm:**
  - This unique feature automatically turns the bath heater ON at a predetermined time.





## REGULATORY COMPLIANCE

- DS 14000 meets all requirements relating to validation, qualification and calibration.
- Appropriate qualification documents (I.Q. / O.Q.) can be supplied with the instrument.

## ADDITIONAL FEATURES (OPTIONAL)

- 12 bowls temperature monitoring system automatically measures and records the temperature of individual vessel at specified sample points.
- Built-in Validation software for RPM & Temperature.
- Recovery Test facility to study 100% Drug Dissolution.

## REPORTS

Selectable Report Format, complying with GLP requirements.

### **RUN REPORT**

- a) Report giving Run No., Set parameters and Actual parameters during the dissolution process.
- b) Diagnostic functionality report to ensure proper working of the system.
- c) Printout of each vessel temperature and paddle/basket speed at every sampling interval for validation.
- d) Validation report for Temperature, RPM



## TYPICAL SPECIFICATIONS

- **Control:** Micro controller based (Advanced version of microprocessor).
- **Display:** 40 x 2 line back lighted liquid crystal display (LCD)
- **Keyboard:** Alphanumeric splash waterproof polyester soft keys.
- **Method Storage:** 15 programs with parameters.
- **Data Storage:** Available with Non-Volatile memory.
- **Water Bath:** 29 litres capacity with built-in water level sensor / Front located drain tap for easy cleaning the water bath.
- **Bath Circulation:** External vibration free water circulator
- **Temperature Range:** 20°C to 55°C
- **Temperature Resolution:** 0.1°C
- **Temperature Accuracy:** up to 45°C  $\pm 0.1^\circ\text{C}$  &  $>45^\circ\text{C}$  up to  $55^\circ\text{C} \pm 0.2^\circ\text{C}$
- **Temperature Sensor:** DTS - Digital Temperature Sensor
- **Paddle/Basket Shaft Speed:** Range 20 to 250 RPM  $\pm 1\%$
- **Dissolution Vessel:** option for Polycarbonate / Glass Vessels (clear, amber, peak vessels, 250, 150 & 100 ml. dissolution vessels available)
- **Sampling Time Selectivity:** Fixed/Programmable (varying intervals)
- **Time Interval Selectivity:** In steps of 1 minute
- **Maximum Number of Intervals:** 30
- **Dissolution Process Time:** 1 min. to 720 hours
- **6 Channel Temperature Reader:** Optional - with Temperature Reader

**Report Format:** a) GLP & Pharmacopeia compliant b) Program parameter report

**Output:** a) **Printer:** Compatible for deskjet, inject and dot matrix printer b) **RS232C:** For PC Connectivity  
c) 21 CFR Part 11 compliance software available (Optional)

- **Power:** 110 / 220 V AC - 50 Hz / 60 Hz
- **Environmental Operating Conditions:** a) **Operation:** Indoor b) **Temperature:** Ambient to 45°C. c) **Humidity:** 5 to 90% non-condensing.
- **Dimensions:** 115 x 60 x 70.5 cms (W x D x H)
- **Weight:** 120 kgs. approx.

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