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BETTER FUNCTIONALITY | BETTER PRECISION | BETTER ANALYSIS

DS 8000 (Auto)

Tablet Dissolution Test Apparatus (6+2)

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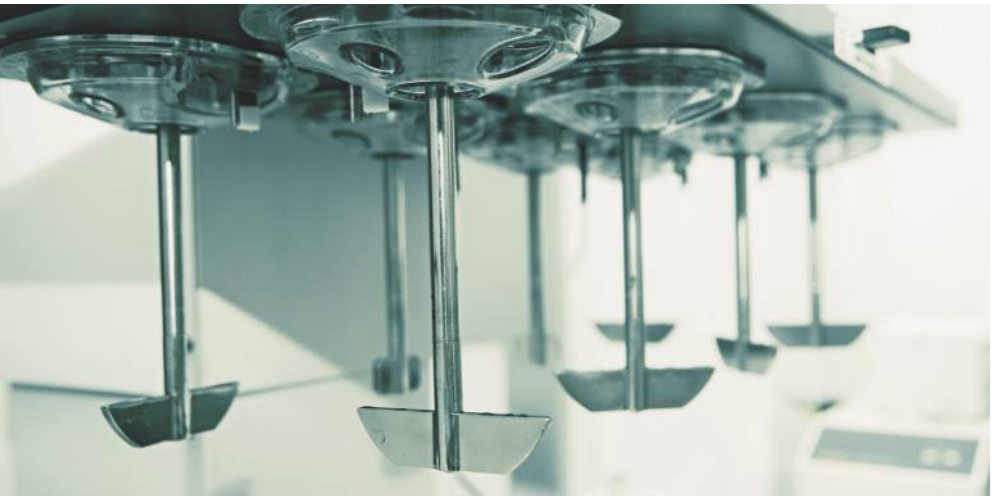
Dissolution Test Apparatus

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 interface, temperature, and solvent composition.

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

This product is designed on the basis of specifications recommended by international regulatory bodies and the future needs of Pharmaceutical Industry. The unit can be used to analyze dissolution profile of tablets, capsules etc. as per USP, BP, IP specifications.



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 6+2 (3+1 & 3+1) vessel configuration enables comparative studies.
- **In-built immersion pump** for uniform water circulation, with audible, low water level alarm, with indication on display for safety.
- **Mono shaft design** with easy changeover between Apparatus I & II eliminates routine height validation as per USP.
- **Paddles, Baskets and Vessels** are laser marked with serial numbers for traceability.
- **Tablet dispenser** - drops 6 dosage form at single instance.
- **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 Easealign 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 an external RTD Temperature Sensor (Pt 100)

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.
  » Validation Software to validate RPM, Temperature, sampling volume & replenish volume.
- **Protects Editing, Avoids invalid entries:**
  » User interactive software in dialogue mode for ease of operation with protection against invalid entries.
  » Multilevel password protection for method editing (10 users)
- **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 8000 meets all requirements relating to validation, qualification and calibration.
- Appropriate qualification documents (I.Q. / O.Q.) can be supplied with the instrument.

INTELLIGENT SAMPLING SYSTEM

- Automated sampling as per USP Specifications. Sampling tubes are lowered in the media only at the time of sampling and withdrawn immediately after sampling, thus no part of the assembly contributes motion, agitation or vibration.
- Sampling tubes are accurately moved to the USP sampling position i.e. a zone mid way between the surface of media and the top of paddle/basket parameters, not less than 1 cm from the vessels wall as selected in the method.
- 6 vessels temperature monitoring system automatically measures and records the temperature of individual vessel at specified sample points.

PERISTALTIC PUMP

- Imported Pump with click-n-go Cassette design provides defined and repeatable occlusion conditions.
- Fixed length pump tubing with stopper for sampling volume accuracy.
- Volume calibration through software.
- Tygon pump tubing for SLS Compatibility with long life.
- High repeatability on all Channels.
- 12 actively driven stainless steel rollers.

SAMPLE COLLECTION

- 10 X 6 or 16 X 6 sets of samples can be collected. For more sampling interval, 24 X 6 collection trays are available.
- Option of 1.5ml & 2ml HPLC vials tray is available.
- Over Head Design for electronic safety and fail safe operation.
- Sensor to locate proper position of tray with alarm facility for collection of sample.
- Wide mouth vial to minimise SLS spillover problem due to foaming characteristics
- Easy positioning with respect to vials or test tube tray for easy changeover

ADDITIONAL FEATURES

- Facility to RINSE the entire sampling path in between sampling time point to eliminate contamination & carryover
- Specially developed cleaning system to clean the entire sampling path after each run.
- Facilities to perform the dissolution test using two buffers (Buffer changing) to cater the application of enteric coating tablets.
- Recovery Test facility to study 100% Drug Dissolution.
- Special software program for calculating % Drug dissolve v/s Time using individual tablet weight.
- Split & on-time interval
- Auto-start in case of power failure

REPORTS

Selectable Report Format, complying with GLP requirements.

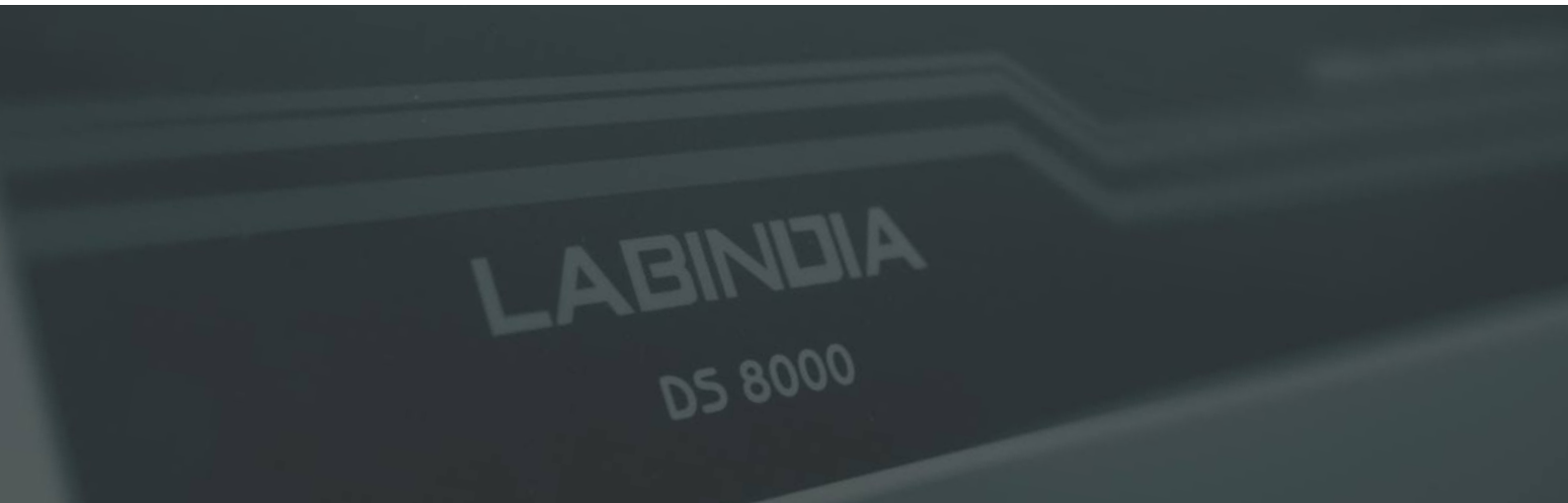
RUN REPORT

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, Sample Volume and Replenishing Volume.



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: 17 litres capacity with built-in water level sensor / Front located drain tap for easy draining of the water bath.
- Bath Circulation: Immersion Pump.
- Temperature Range: 30ºC to 40ºC
- Temperature Resolution: 0.1ºC
- Temperature Control Accuracy: ±0.1ºC
- Temperature Sensor: Pt-100 (RTD)
- Paddle/Basket Shaft Speed: Range 20 to 250 RPM ±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
- Sampling Volume Range: 0.5 - 25.5 ml (Higher volume available)
- Replenishing mode selectivity: User selectable
- Rinsing Functionality: Optional
- Maximum Number of Intervals: 30
- Dissolution Process Time: 1 min. to 720 hours

Report Format:

a) GLP & Pharmacopeia compliant b) Program parameter report
c) Evaluation software, which includes: • Evaluation Prog. Parameter • Evaluation Report • Dissolution Profile

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 45ºC. c) Humidity: 5 to 90% non-condensing.
- Dimensions: 71.5 x 60 x 70.5 cms. (W x D x H)
- Weight: 80 kgs. approx. (Basic Dissolution System)

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