LABINDIA
ANALYTICAL
WHERE COMMITMENT IS CULTURE

BLUE SERIES

TABLET DISSOLUTION TEST APPARATUS

DS 14000+

with Syringe Pump

www.labindia-analytical.com

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.

STANDARD FEATURES

- **Advanced, Micro-Controller based:** User-friendly, complies with current USP, BP, IP & EP specifications.
- **Splash waterproof keyboard:** Alphanumeric polyester soft keys for keyboard.
- **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 marked with serial numbers for traceability.
- **Tablet dispenser -** drops 12 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 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.
  » Validation Software to validate RPM, Temperature, sampling volume & replenish volume.
- **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 powerinterruption (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.

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 (500, 750, 900 & 1000 ml).
- 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.
- 12 bowls temperature monitoring system automatically measures and records the temperature of individual vessel at specified sample points.

SYRINGE PUMP FOR AUTOMATIC DISSOLUTION TEST

- Multi-Syringe Pump system designed for automatic Sample Collection from Dissolution Bowls of Labindia Dissolution Test Apparatus Ds14000+.
- Perform Rinsing the sample tubing path, Replenishing the blank media volume to bowls and Sample Dilution tasks (Optional for future development)
- Controlled through Labindia dissolution Instrument Controller with Operation Status Indications on the front panel for user information.
- Inert fluid path consisting of Teflon carrier tubing, Gastight Glass Syringes with Teflon Plunger and PEEK body Valves.
- Proprietary high-efficiency and maintenance-free Stepper motor drive system.
- Long-life 4 port Rotary shear valves with SS Body
- Volume accuracy better than 2%.
- Built in Clean function executed at the end of each test to ensure the entire liquid path is clean for the next run avoiding cross contamination and carryover effects.
- Validation protocol to validate the Sample, Replenishing, Rinse Volume
- All syringes & valves operated synchronously for parallel selection.
- Zero setting for each syringe.

SPECIFICATIONS

- No. of Syringes=12 (Gastight, ZDV syringes with PTFE Plunger tip)
- Syringe Volume= 12.5ml
- Valves= 4 Port, Fluro Polymer Inert Rotary valves with SS body
- Syringe Drive= Stepper motor based.
- Volume= 0.5mL to 10.5mL. Programmable.
- Sampling Accuracy= Better than ±2% without tubings
- Min. Sample Interval (10mL)= 5 mins: with TR & Vol. Replenishing,
- Carrier Tubing type= Teflon, 1/16" OD
- Interface= RS232C - Proprietary for Labindia DS8000+/DS14000+.
- Power requirements= 90-270Vac, 60/50Hz. 50W

SAMPLE COLLECTION

- 12 X 6 X 2 sets of samples can be collected. For more sampling interval, 24 X 6 collection trays are available.
- Option of 1.5ml & 2ml HPLC vials 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

ADDITIONAL FEATURES

- Facility to RINSE the entire sampling path in between sampling time points to reduce 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.
- Split & on-time interval

REPORTS

Selectable Report Format, complying with GLP requirements.

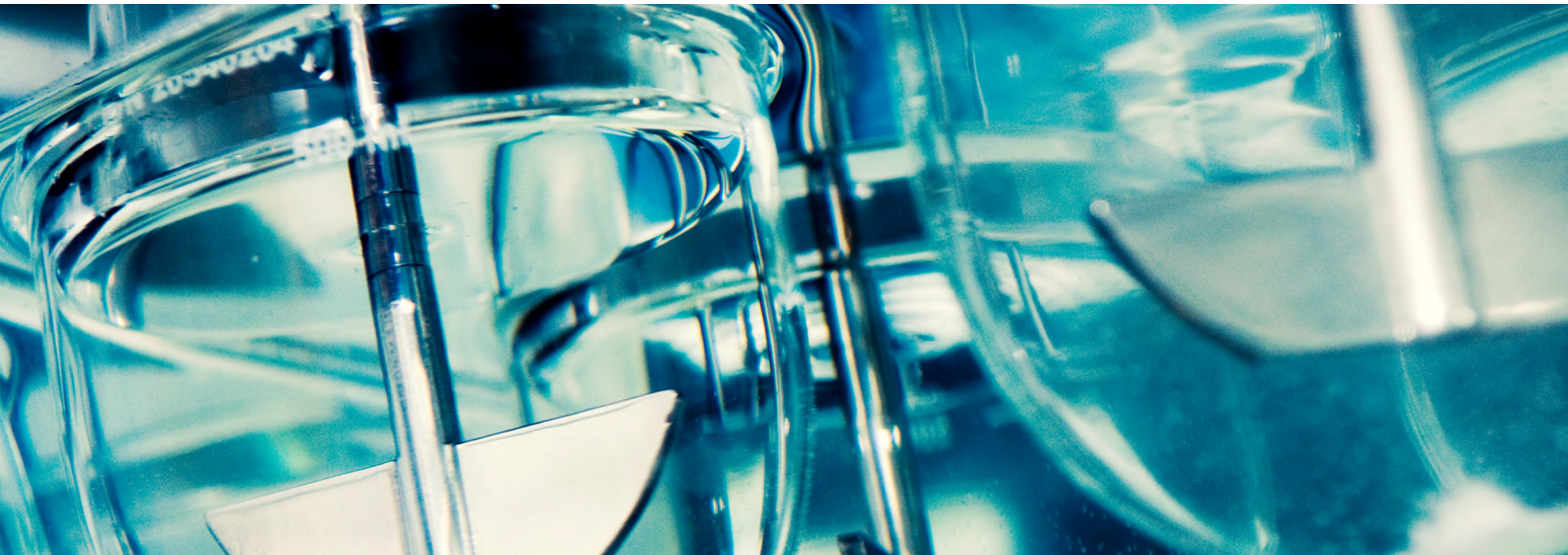
RUN REPORT

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	29 litres capacity with built-in water level sensor.
Bath Circulation	External vibration free water circulator
Temperature Range	20°C to 55°C
Temperature Resolution	0.1° C.
Temperature Control Accuracy	up to 45°C ±0.1°C & >45°C up to 55°C ±0.2°C
Temperature Sensor	DTS - Digital Temperature Sensor
Evaporation Loss	1% (at 50 RPM / 37°C / 1000mL / 24hrs)
Paddle/Basket Shaft Speed Range	20 to 350 RPM
RPM Speed Accuracy	20 to 300 RPM ±0.5 RPM & Above 300 RPM ± 0.8 RPM
Dissolution Vessel	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 - 10 ml
Replenishing mode selectivity	User selectable.
Maximum Number of Intervals	30
Dissolution Process Time	1 min. to 720 hours.
6 Channel Temperature Reader	Built-In
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	210-230 V AC ± 10%, 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	140 kgs. approx.

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Striving to become the best individuals, we endeavour to foster the best team. Performing sensibly, we try to achieve the best efficiency. Working innovatively, we seek to make the best products. Listening patiently, we excel to offer the best service. So, no matter what your needs are, come to us, **GET THE BEST**