

TABLET DISSOLUTION  
TEST APPARATUS  
**DS 14000**  
(with Piston Pump)  
**SMART**

BLUE  
SERIES



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 (ARM Core):**

- » User-friendly, complies with current USP, BP, IP, JP & EP specifications.

- Moulded water bath with 12+2 (6+1 & 6+1) vessel configuration enables comparative studies.
- Mono shaft design with easy changeover between Apparatus I & II eliminates routine height validation as per USP.
- Automatic stirrer 25 mm depth positioning (as per USP requirement)
- Paddles, Baskets and Vessels are laser marked with serial numbers for traceability.
- Automated Tablet dispenser - drops 12 dosage form at single instance.

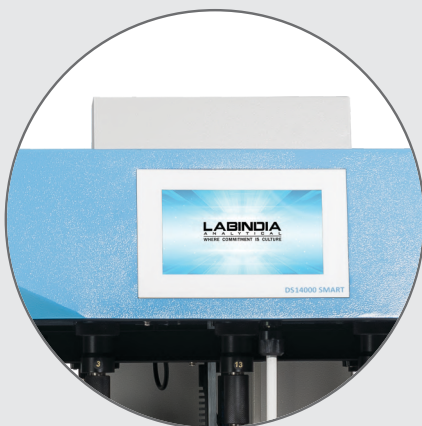
- **Low Evaporation Lids:**

- » 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 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 an external RTD Temperature Sensor (DTS - Digital Temperature Sensor)

7" colour  
high resolution Display  
with touch screen  
interface



External  
vibration free  
flow Water Circulator



## SOFTWARE

- **GLP Compliance:**

- » QWERTY Keyboard for alphanumeric entries of Sample Name, Sample Number & Identification Number and parameters for authentication
- » Built-in Real Time Clock (RTC) for date and time on display and on printout.
- » Factory entered CUSTOMER NAME with Instrument Serial Number on report printouts make the system foolproof.
- » Non-Volatile Solid State memory storage for 1000 Test methods with parameters
- » Validation Software to validate RPM, Temperature, sampling volume & replenish volume.

- **Protects Editing, Avoids invalid entries:**

- » User interactive software for ease of operation with protection against invalid entries.
- » Multilevel password protection for method editing.

- **Ease in operation:**

- » 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.

## PUMP SYSTEM - PP 12

- Piston Pump - PP 12 is Microprocessor controlled and is ideal for sample withdrawal from 12 channels
- The Piston Pump - PP 12 with inert ceramic rotor overcomes all absorption issues
- Accuracy better than 0.2 (@10mL)
- Rinse function for reducing carryover issues
- Surfactant Media Compatibility.
- Option of sample dilution available (not recommended before final filtration)



## SAMPLE COLLECTION

- 12 X 8 X 2 sets of samples can be collected. For more sampling interval, 24 X 8 collection trays are available.
- Option of 1.5mL & 2mL HPLC vial tray is available.
- 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



## 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.
- 12 vessels temperature monitoring system automatically measures & records the temperature of individual vessel at specified sample points.
- Inert PTFE Fluoropolymer Carrier Tubing

## ADDITIONAL FEATURES

- Built-in Validation software.
- 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 3 buffers (Buffer changing) to cater the application of enteric coating tablets
- Recovery Test facility to study 100% Drug Dissolution.
- Split & on-time interval
- Disposable Syringe & Filter attachment for manual sample collection.

## OPTIONAL ACCESSORIES

- Sinkers, USP 5 - Transdermal Paddle Over disk), USP 6 (Transdermal Rotating Cylinder), Intrinsic dissolution apparatus (rotating and stationary), Enhancer cell, Felodipine Basket, Sampling Cannula, Teflon coated Paddles, Gold plated Baskets.
- Dissolution test vessel : Peak Vessel 1000mL, 100mL, 150mL, 250mL & 500mL with mini paddles
- Dissolution Qualification tool kit for mechanical calibration according to FDA

## REPORTS

Report Format, complying Run, Date and Time with GLP requirements

### • RUN REPORT

- » Report giving Run No., Set parameters and Actual parameters during the dissolution process
- » Printout of each vessel temperature and paddle/basket speed at every sampling interval for validation
- » Validation report for Temperature, RPM, Sample Volume and Replenishing Volume

## 21 CFR Part 11 COMPLIANCE

- Audit Trail for all activities with search facility, report generation and printing
- 200 & More User ID's with alphanumeric entries of user name, password and role based privileges selection
- Multi-level roles with password protection, expiry & complexity
- User authentication is performed for each and every operation done by user
- PDF report file can be created through print
- USB Printing eliminates the need of serial port to connect with instrument.  
The user can take printout on any local or network printer as well
- Electronic signature functionality
- Data Backup & Restore facility available
- LAN (Ethernet) connectivity for Data backup on Network shared folder



## TYPICAL SPECIFICATIONS

Control	Micro Controller
Method Storage	Minimum 1000 methods with parameters
Data Storage	Available with Non-Volatile memory. More than 10,000 reports
Software Compliance	21 CFR Part 11
Temperature Range	20°C to 55°C
Temperature Accuracy	up to 45°C $\pm 0.1^\circ\text{C}$ & $>45^\circ\text{C}$ up to 55°C $\pm 0.2^\circ\text{C}$
Temperature Resolution	0.1°C
Temperature Sensor	DTS - Digital Temperature Sensor
Evaporation Loss	1% (at 50 RPM / 37°C / 1000mL / 24hrs)
Display	7" high resolution display with capacitive touch screen
Paddle/Basket Shaft Stirring Speed	20 to 250 RPM ( $\pm 0.5$ RPM)
Sampling Time Selectivity	Fixed / programmable (Varying Intervals)
Time Interval Selectivity	In steps of 1 Minute
Sampling Volume Range	0.5 - 22.0 mL
Vessel Capacity	1000 mL
Water Bath	29 litres capacity with built-in water level sensor / front located drain tap for easy draining of the water bath
Maximum Number Of Intervals	50
Dissolution Process Time	1 min to 1200 hrs
Print Interface	USB / WiFi Direct enabled Printer
Data Backup Interface	USB / LAN Port
Electrical Power	110/220V AC - 50 Hz/60 Hz
Dimension (W*D*H)	115*60*70.5 cm
Weight	120 kg Approx
Dissolution Vessel Options	Polycarbonate /Glass Vessels (Clear and Amber)

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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**

LABINDIA reserves the right to change specification without notice as part of its continuous programme of product development.