

# DS 14000 (with Piston Pump) SMART

Tablet Dissolution Test Apparatus (12+2)



21 CFR  
PART 11  
FULLY  
COMPLIANT



The new LABINDIA Dissolution Apparatus DS 14000 provide great versatility and configurability. The state-of-the-art Dissolution Testing with touch screen is elegant in design and user friendly with advanced features. The DS 14000 is precision engineered for USP<711> dissolution for ease of use. It fulfils all requirements relating to ASTM & FDA Mechanical Calibration.

Diagnostic functionality and validation report of the system is reliable enough for QC applications and flexible for R&D use.

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## 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.

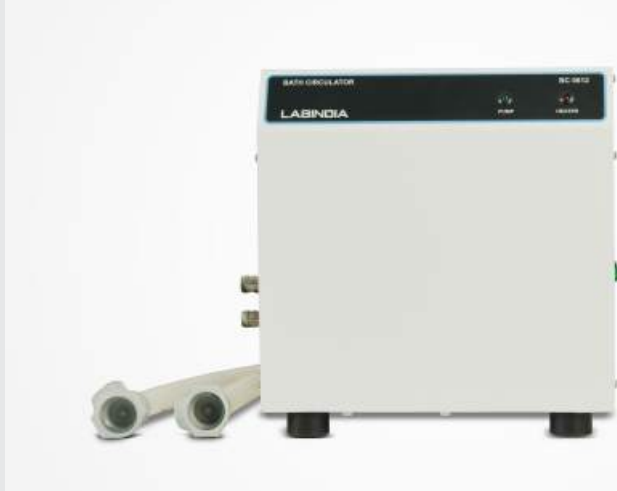
- **State-of-the-art design:**

- » 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 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 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 ideal for sample withdrawal from 12 channels
- The Piston Pump - PP 12 with inert ceramic rotor overcomes all absorption issues
- Accuracy better than  $\pm 2\%$  (@10mL)
- Rinse function for reducing carryover issues
- Surfactant Media Compatibility.



## 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

<b>Control</b>	Micro Controller
<b>Method Storage</b>	200+ methods with parameters
<b>Software Compliance</b>	21 CFR Part 11
<b>Temperature Range</b>	20°C to 55°C
<b>Temperature Accuracy</b>	up to 45°C $\pm 0.1^\circ\text{C}$ & $>45^\circ\text{C}$ up to 55°C $\pm 0.2^\circ\text{C}$
<b>Temperature Resolution</b>	0.1°C
<b>Temperature Sensor</b>	DTS - Digital Temperature Sensor
<b>Evaporation Loss</b>	1% (at 50 RPM / 37°C / 1000mL / 24hrs)
<b>Display</b>	7" high resolution display with capacitive touch screen
<b>Paddle/Basket Shaft Stirring Speed</b>	20 to 350 RPM (20 to 250 $\pm 1$ , 251 to 350 $\pm 2$ )
<b>Sampling Time Selectivity</b>	Fixed / programmable (Varying Intervals)
<b>Time Interval Selectivity</b>	In steps of 1 Minute
<b>Sampling Volume Range</b>	0.5 - 22.0 mL
<b>Vessel Capacity</b>	1000 mL
<b>Water Bath</b>	29 litres capacity with built-in water level sensor / front located drain tap for easy draining of the water bath
<b>Maximum Number Of Intervals</b>	50
<b>Dissolution Process Time</b>	1 min to 1200 hrs
<b>Print Interface</b>	USB / WiFi Direct enabled Printer
<b>Data Backup Interface</b>	USB / LAN Port
<b>Electrical Power</b>	110/220V AC - 50 Hz/60 Hz
<b>Dimension (W*D*H)</b>	115*60*70.5 cm
<b>Weight</b>	120 kg Approx
<b>Dissolution Vessel</b>	Polycarbonate /Glass Vessels (Clear and Amber)

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