TYPICAL SPECIFICATIONS

Control	Micro Controller
Method Storage	Minimum 1000 methods with parameters
Software Compliance	21 CFR Part 11
Temperature Range	20˚C to 55˚C
Temperature Accuracy	up to 45°C ±0.1°C & >45°C up to 55°C ±0.2°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 350 RPM (20 to 250±1, 251 to 350±2)
Sampling Time Selectivity	Fixed / programmable (Varying Intervals)
Time Interval Selectivity	In steps of 1 Minute
Vessel Capacity	1000 mL
Water Bath	29 litres capacity with built-in water level sensor / front loaded 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 Option	Polycarbonate /Glass Vessels (Clear and Amber)

LABINDIA ANALYTICAL
WHERE COMMITMENT IS CULTURE

www.labindia-analytical.com / For Enquiries: sales.mfd@labindia.com

Labindia Analytical Instruments Pvt. Ltd.

HEAD OFFICE:
Thane: 201, Nand Chambers, LBS Marg, Near Vandana Cinema, Thane (W) - 400 602. **Tel.:** +91-22-2598 6000 / 2598 6110 **E-mail:** sales.mfd@labindia.com

REGIONAL OFFICES:
Delhi: Tel.: +91-11-4330 6001 / 10 **Chennai: Tel.:** +91-44-2434 7008 / 2432 0352 **Kolkatta: Tel.:** +91-33-2466 3362

BRANCH OFFICES:
Bangalore: Tel.: +91 80 4565 6200 **Lucknow: Tel.:** +91-522-2346 535 / 2346 496 **Hyderabad: Tel.:** 040 4444 3530
Vadodara: Tel.: +91-265-2986 005 / 2986 006 **Pune: Tel.:** +91-20-2545 3386 **Chandigarh: Tel.:** +91-172-4090 001-07 / 4090 009

FACTORY 1: Plot No. EL-72, Electronic Zone, TTC Industrial Area, Thane Belapur Road, Navi Mumbai - 400 705.**Tel.:** +91-22-6107 6666

FACTORY 2: Plot No. W-401, TTC, MIDC Industrial Area, Rabale, Thane-Belapur Road, Navi Mumbai 400 701. **Tel.:** +91-22-6107 6555

APPLICATION & TRAINING CENTRE: R-909, TTC Industrial Area, Thane Belapur Road, Rabale, Navi Mumbai - 400 701. **Tel.:** +91-22-6107 6555

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BLUE SERIES

TABLET DISSOLUTION TEST APPARATUS (12+2)

DS 14000 (Auto) SMART

21 CFR PART 11 FULLY COMPLIANT

The new LABINDIA Dissolution Apparatus DS14000 provide great versatility and configurability. It fulfils all requirements relating to ASTM & FDA Mechanical Calibration. The state-of-the-art Dissolution Testing with touch screen is elegant in design and user friendly with advanced features. The DS14000 is precision engineered for USP<711> dissolution for ease of use.
Allows storage of up to 1000 product test run parameters.

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

STANDARD FEATURES

- **Advanced, Micro-Controller based:**
  User-friendly, complies with current USP, BP, IP & 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.
- 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 &
inbuilt UV light to reduce contamination

SOFTWARE

- **GLP Compliance:**
  » QWERTY Keyboard for 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 1000 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:**
  » 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.

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

- 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.

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 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.

21 CFR Part 11 Compliance

- Audit Trail for all activities with search facility, report generation and printing
- 200 User ID's with alphanumeric entries of user name, password and role based privileges selection
- Multi-level roles with password protection
- User authentication is performed for each and every operation done by user
- Customizable 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
- Manual Archive and Data Backup facility available