

TABLET DISSOLUTION
TEST APPARATUS
DS 8000
(Basic)
SMART

BLUE
SERIES



21 CFR
PART 11
FULLY
COMPLIANT

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 6+2 (3+1 & 3+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 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 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



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
- Factory entered CUSTOMER NAME with Instrument Serial Number on report printouts make the system foolproof
- Non-Volatile memory storage of 1000 test methods with parameters

- **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
- Built in report data storage facility
- Error indication helps user to trace the problem

Protects Editing, Avoids invalid entries:

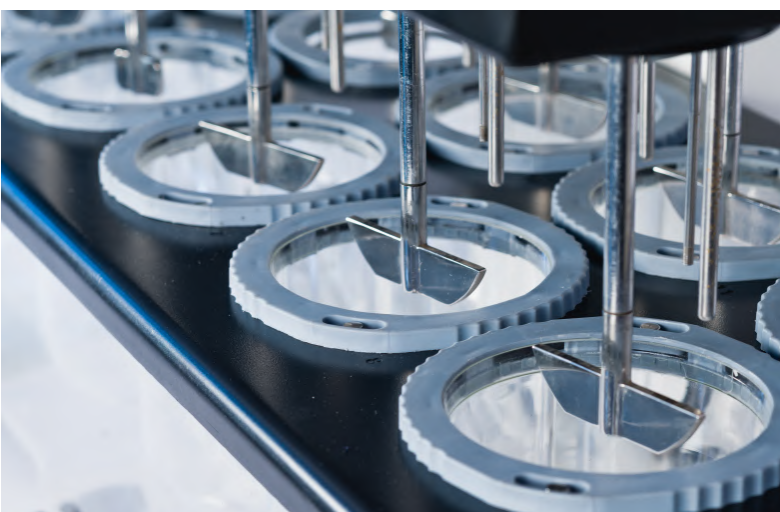
- User interactive software for ease of operation with protection against invalid entries.

Alarms and Indications:

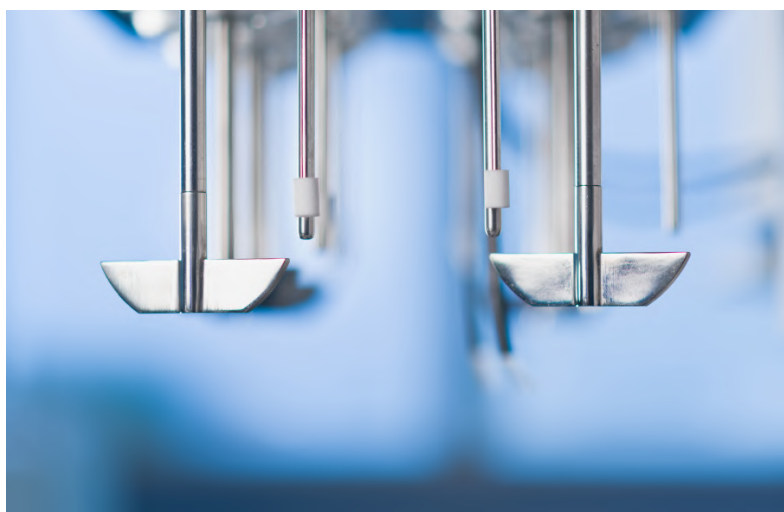
- Audible indication for ready state of instrument.

Wake-up Alarm:

- This unique feature automatically turns the bath heater ON at a predetermined time.



Bionet Locking



Temperature Up To 55°C

Additional Features (Optional)

- Sinkers, USP 5 (Transdermal Paddle Over disk), USP 6 (Transdermal Rotating Cylinder), Intrinsic dissolution apparatus (rotating and stationary), Enhancer cell, Felodipine Basket, Sampling Cannula
- Dissolution test vessel 100mL, 150mL, 250mL & 500mL with mini paddles
- Dissolution qualification tool kit for mechanical calibration according FDA
- Qualification document (IQ and OQ)

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 and 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 (± 0.5 RPM)
Sampling Time Selectivity	Fixed / programmable (Varying Intervals)
Time Interval Selectivity	In steps of 1 Minute
Vessel Capacity	1000 mL
Water Bath	17 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)	71.5*60*70.5 cm
Weight	80 kg Approx
Dissolution Vessel Option	Polycarbonate / Glass Vessel (Clear & 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.