

TABLET DISSOLUTION TEST APPARATUS

DS 14000 (Basic)

**SMART** 





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)





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.





### **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 & 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
Software Compliance	21 CFR Part 11
Temperature Range	20°C to 55°C
Temperature Accuracy	up to $45^{\circ}\text{C} \pm 0.1^{\circ}\text{C} \& >45^{\circ}\text{C}$ up to $55^{\circ}\text{C} \pm 0.2^{\circ}\text{C}$
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 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 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 Option	Polycarbonate /Glass Vessels (Clear and Amber)



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