

# LABINDIA

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SERVICE MANUFACTURING PRECISION MANUFACTURING  
VALUE PRECISION VALUE SERVICE  
MANUFACTURING QUALITY SERVICE  
VALUE QUALITY SERVICE

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Tablet Dissolution Test Apparatus

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Sample Processor (Diluter / Dispenser)

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Tablet Disintegration, Friability, Hardness & Tap Density Tester

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Automatic Titrator / Karl Fischer Titrator

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Melting Range Apparatus

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pH / Conductivity / TDS Meter

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UV VIS Spectrophotometer



# Our Clientele Growing Everyday





# Tablet Dissolution Test Apparatus

## DS 8000<sup>+</sup>



### Genesis of New Edge DS 8000+ System.

Dissolution is considered one of the most important Quality control (QC) test performed on pharmaceutical dosage forms. Dissolution is proven tool for predicting in- vivo & in-vitro co-relation & leverage expensive clinical studies to determine bioequivalence for all strengths except RLD (Reference Listed Drug).

The dissolution testing of almost every oral solid drug product leads to a turbid or hazy solution. Sample withdrawal from dissolution vessels must be followed by a filtration step to get rid of un-dissolved components and eliminate potential interference during quantification by UV/VIS spectrophotometer or HPLC.

Manual dissolution testing process is time-consuming for sample preparation, such as sample collection, filtration and related human errors.

The main concern of today's analyst is cumbersome sample filtration process for UV and HPLC analysis of Multipoint Dissolution. The filters get blocked after every use & needs to be replaced with new, after each sampling interval.

It is experienced that sample filtration through the 0.45  $\mu$  filter by conventional design of peristaltic pump or syringe pump is almost impossible. Our New invention has proved that filtration through 0.2  $\mu$  by high pressure piston pump is easy, time saving and accurate. This thereby helps reduce motion waste in QC and increases productivity. This thought gave birth to the new system DS 8000+ consisting of dissolution bath, Piston pump, filter changer and sample collector.

### LABINDIA Dissolution Basic Model Features

- Advance Microcontroller based system compiles with the latest USP/EP/ BP/ FDA regulations
- System having modulated water bath with 6+2 (3+1, 3+1) vessels configuration enables comparative studies.
- Monoshaft design, simply screw the paddles or baskets in the appropriate stirring elements, with no further height adjustment required to comply with USP.
- All stirring elements are laser mark with Serial No. for authentication.
- Tablet Dispenser with Low evaporation lids to reduce the media loss during long run.
- Vessel centering collar assures the vessels sits flat and parallel to the axis of the shaft to comply USP guidelines for vessel verticality and centering
- ICH compliant software with non-volatile memory storage of 15 methods.
- Individual vessel temperature monitoring at designated time point to comply with USP requirements (optional)
- Built in validation software to validate RPM, Temperature sampling & replenishing value.
- Recovery test to study 100% Drug Dissolution
- Parallel port for Printer & PC compatibility for Data downloading.



# with Piston Pump & Automatic Filter Changer: DS 8000<sup>+</sup>

## Piston Pump - PP 08



## Filter Changer - FC 08



### **Piston Pump-PP08**

#### **Accessory for Automatic Sample Withdrawal - High Pressure Pump System**

##### **Features**

- Piston Pump-PP08 is Microprocessor controlled and is ideal for sample withdrawal from 6, 7, or 8 channels.
- Piston Pump-PP08 eases filtration of sample before collection by using 0.2 µm filters Luer tip Syringe filters. (fulfils the regulation of US Pharmacopeia and other Pharmacopeias)
- The Piston Pump-PP08 with inert ceramic rotor overcomes all absorption issues
- High flow rates of 25 ml/min can be achieved with accuracy better than 1%
- Rinse function for reducing carryover issues.

### **Filter Changer-FC 08**

#### **Optional Accessory for Inline Filtering of Sample before collection through Syringe Filters**

##### **Features**

- Automatic Filter changer FC 08 is Microprocessor controlled and designed to filter 6, 7, or 8 sampling lines simultaneously.
- FC 08 is used in conjunction with high pressure LABINDIA Piston Pump-PP08 with filtration down to 0.2 µm.
- Filter changer FC 08 is perfect for Online UV VIS or offline sample collection for HPLC Analysis
- The FC 08 unit is configured directly in line with the sample withdrawal system
- High Storage capacity - upto 96 filters at a time gives uninterrupted filtered sample collection for 16 Sampling Points (can be extended to 20 sampling points)
- Automated filter changing of used membrane filters with new ones between each sampling interval. Eliminates issues like filter clogging, saturation or carryover.
- Uses standard syringe type 25 mm disposable Luer tip filters
- Used filters are automatically removed and collected in a container after completion of each cycle





# Basic Tablet Dissolution Test Apparatus

DS 14000 (Manual)



DS 8000 (Manual)



Dissolution Tests are very important pharmaceutical quality control tool as they are conducted to determine the drug pattern, physiological availability & Bioavailability of formulated drug products. To carry out precise & efficient drug dissolution studies, LABINDIA brings to you the state-of-art designed Tablet Dissolution Testers which are uniquely designed to support USP 1, 2, 5 & 6 and are compliant with the latest Pharmacopeias (USP/ BP/ IP). Apparatus for Intrinsic test & Stationary basket methods are also available.

## Standard Features:

- Vessel Configuration: DS8000 (6+2 bowl system ) and DS14000 (12+2 bowl system) available
- Advanced microcontroller based user friendly state-of-the-art product design with alphanumeric splash waterproof polyester soft keys
- Moulded water bath with built in immersion pump for uniform water circulation with audible, low water level alarm with indication on display for safety
- Mono shaft design allows easy changeover between Apparatus I & II thus eliminates routine height validation check as per USP
- Laser marked serial numbers on Paddles, Baskets & Vessels for traceability
- Glass vessels with moulded flange to ensure the centering of the shaft with respective vessel
- Facility to monitor vessel temperature with an external RTD temperature sensor (Pt100)

## Software:

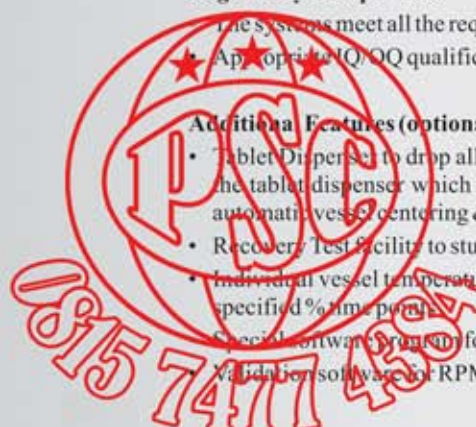
- User interactive software in dialogue mode for ease of operation with protection against invalid entries
- GLP Compliant report format with alphanumeric entries of Sample name, number & identification number for authentication.
- Non-Volatile Memory storage of 15 methods with parameter
- Dissolution RUN can be started with last run parameters
- Wake-up alarm feature automatically turns the bath heater ON at a predetermined time
- RS 232C Interface for PC connectivity & Parallel port for printer
- Auto-start in case of power failure

## Regulatory Compliance:

- The systems meet all the requirements relating to validation, qualification & calibration
- Appropriate IQ/OQ qualification documents can be supplied with the instrument

## Additional Features (optional):

- Tablet Dispenser to drop all the dosage form at single instance along with Conical shaped low evaporation recovery lids on the tablet dispenser which reduces the media loss during long dissolution run and Integrated pre-centered lids to ensure automatic vessel centering & precise positioning of paddle/basket with shaft without any tool (as per pharmacopeia)
- Recovery Test Facility to study 100% drug dissolution
- Individual vessel temperature monitoring system automatically measures & records the temperature of individual vessel at specified % time points
- Special software program for calculation Percent D v/s Time using individual tablet weight entry
- Validation software for RPM & Temperature



# Automatic Tablet Dissolution Test Apparatus ( Peristaltic pump)

## DS 14000 (Auto)



## DS 8000 (Auto)



### Features of Basic Tablet Dissolution Test Apparatus (Mentioned on Page 4 & 6)

#### PLUS

#### Intelligent Sampling system:

Intelligent motorized sampling manifold complies with USP requirements

Temperature monitoring system automatically records temperature of all the individual vessels at specified time points

#### Peristaltic Pump:

- Bi-directional 12 channel -DS 8000 (6+2 bowl system) and 24 channel -DS 14000 (12+2 bowl system) peristaltic pump with tubing from ISMATEC, Switzerland
- Imported pump with click-n- go Cassette design along with volume calibration through software.

#### Sample Collection:

- Over Head Design for electronic safety & fail safe operation
- Sensor to locate proper position of tray with alarm facility for collection of sample
- For DS 8000(6+2 bowl system) : 10x6 or 16x6 sets of samples can be collected. For more sampling interval, 24x6 collection trays are available in the system. For DS 14000 (12+2 bowl system) : 12 x 6 x 2 sets of samples can be collected
- Option of Test-tubes & 1.5ml / 2ml HPLC vials tray are available

#### Additional Features:

- Facility to perform the dissolution test using two buffers (buffer changing) to cater the application of enteric coating tablets
- Special software program for calculation Percent D v/s Time using individual tablet weight entry
- Split & on-time interval
- Auto-start in case of power failure





## DS 14000 with Piston Pump



### Features of Basic Tablet Dissolution Test Apparatus (Mentioned on Page 4&6)

#### PLUS

#### PUMPSYSTEM - PP12

- 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
- High flow rates of 25 ml / min can be achieved with accuracy better than 1%
- Rinse function for reducing carryover issues
- Surfactant Media Compatibility.

## DS 8000 with Piston Pump



### Features of Basic Tablet Dissolution Test Apparatus (Mentioned on Page 4 & 6)

#### PLUS

#### PUMPSYSTEM - PP08

- Piston Pump - PP 08 is Microprocessor controlled and is ideal for sample withdrawal from 6 channels
- The Piston Pump - PP 08 with inert ceramic rotor overcomes all absorption issues
- High flow rates of 25 ml / min can be achieved with accuracy better than 1%
- Rinse function for reducing carryover issues
- Surfactant Media Compatibility.

### 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.
- 6 vessels temperature monitoring system automatically measures & records the temperature of individual vessel at specified sample points.

### SAMPLE COLLECTION

- 10 X 6 or 16 X 6 sets of samples can be collected. For more sampling interval, 24 X 6 collection trays are available.
- Option of 1.5ml & 2ml HPLC vial tray is available.
- Cover Latch Design for electronic safety and fail safe operation
- 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



## DS 14000 with Syringe Pump



### Features of Basic Tablet Dissolution Test Apparatus

*(Mentioned on Page 4 & 6)*

**PLUS**

### Features of Sample Collection & Intelligent Sampling System

*(On Page 8)*

**PLUS**

### C3000X12 Syringe Pump For Automatic Dissolution Test Sample Collection.

- 12 port Multi-Syringe Pump system designed for automatic Sample Collection from Dissolution vessels of Labindia Dissolution Test Apparatus DS 14000
- Proprietary high efficiency & maintenance free stepper motor drive system
- Inert fluid path consisting of Teflon carrier tubing, Gas tight Glass Syringes with Teflon Plunger and PEEK body Valves.
- Long-life rotary shear valves (up to 24 times the life of competing valves)
- Compatible with Surfactant Media
- Easy Serviceability and syringe maintenance
- Easy calibration and Validation with built-in method
- Volume accuracy better than 1%.

## DS 8000 with Syringe Pump



### Features of Basic Tablet Dissolution Test Apparatus

*(Mentioned on Page 4 & 6)*

**PLUS**

### Features of Sample Collection & Intelligent Sampling System

*(On Page 8)*

**PLUS**

### C3000x6 Syringe Pump For Automatic Dissolution Test Sample Collection.

- 6 port Multi-Syringe Pump system designed for automatic Sample Collection from Dissolution vessels of Labindia Dissolution Test Apparatus DS 8000
- Proprietary high efficiency & maintenance free stepper motor drive system
- Inert fluid path consisting of Teflon carrier tubing, Gas tight Glass Syringes with Teflon Plunger and PEEK body Valves.
- Long-life rotary shear valves (up to 24 times the life of competing valves)
- Compatible with Surfactant Media
- Easy Serviceability and syringe maintenance
- Easy calibration and Validation with built-in method
- Volume accuracy better than 1%.





# ACCESSORIES

150 ml. Small Volume Kit



Glass Bowl with Rings



Metformin Tablet Holder (USP)



Adjustable Sampling Cannula



Intrinsic Dissolution



Paddleover Disc - USP 5



Stationary Basket ( for Felodipine Tablet )



Mini Paddles



Sinkers



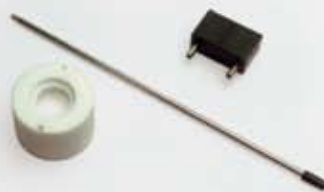
## Other Accessories

- Mini Vessels (150 ml. & 250 ml.)
- Enhance Cell for Ointment
- Peak Vessels
- Metformin Tablet Holder
- Validation Kit (Includes):
  - Temperature Indicator
  - Tachometer
  - Wobble Test Kit
  - Vibration Meter
  - Centering
  - Variable Depth Gauge

Transdermal Cylinder (Rotating) (USP 6)



Enhancer Cell for Ointments



Wobble Test Kit



Tachometer



Digital Protractor



Vibration Meter



Variable Vernier Depth Gauge



Inside Divider



## Sample Processor (Diluter / Dispenser)



### Features

- Unique Automatic Sample Preparation System for Dissolution Test Apparatus reduces time consuming manual steps of Sample Dilution
- User selectable Dilution factor
- Precision Gas Tight Syringe based Burette system improves precision and accuracy of the analysis
- Advance Micro-controller based user-friendly, state-of-the-art product design with alphanumeric splash waterproof polyester soft keys for keyboard. User interactive software in dialogue mode for ease of operation with protection against invalid entries
- Dual Tray - 16 x 6 positions Standard Bottles 15 ml (96 nos), consisting of One Sample Tray and another tray for Diluted samples. Specially deigned for Dissolution test. Optional trays will be available for HPLC vials for the Diluted sample
- Non-Volatile memory storage of 25 methods with parameters and Alphanumeric entries of Sample Name and Identification Number for authentication.
- Run can be performed continuously up to 96 Samples dilutions
- Daily Auto Incremented Run Number and Factory entered CUSTOMER NAME with Instrument Serial Number on report makes system fullproof and GLP complaint
- Validation / Calibration protocol for Volume validation and Dilution verification
- Error indication on display with Audible alarm helps user to trace the problem
- Printer Compatibility for Deskjet, Inkjet & Dot-matrix printer
- Ethernet Connectivity by RE01 Module and EDC80 Data capture Software (Optional)

## UV-Vis Spectrophotometer 3000+



### Features

- Accurate analysis: Holographic grating greatly reducing stray light of the instrument and making the analysis more accurate.
- Stable performances: The double beam optics ensures good stability.
- High-speed measurement: The fastest scanning speed is over 1000nm.
- Powerful function: The main unit of the spectrophotometer can analyse for photometric measurement, quantitative measurement, spectrum scan, DNA/Protein analysis and can print data. When connected to a computer the UVWin software adds many additional functions, such as 3D spectrum analysis, GLP laboratory protocol. It can be applied in pesticide residue detection, environment protection, inspection, quarantine & other fields. 21 CFR Part 11 compliance software (optional).
- Convenient operation: High degree of automation, the operator only needs to press keys twice when measuring ordinary samples.
- Easily upgraded: Many optional accessories enhance the flexibility and the measurement range of the instrument.
- Easy routine maintenance: The simple mechanical structure and modular electrical design make the routine maintenance easy.
- Original technology: The deuterium and tungsten lamps can be easily replaced and are supplied pre-aligned.





# Tap Density Tester



## Features

- Advanced microcontroller based user friendly, state-of-the-art product design with alphanumeric splash waterproof polyester soft keys. User interactive software in dialogue mode.
- Meets USP, IP, ASTM, etc specifications
- Gives calculated results i.e. Tapped Density, Compressibility Index, Hausner Ratio & Bulk Density
- Two Tapping position for 14mm & 3mm with Cylinder holder to hold 100ml & 250 ml cylinders
- Balance Interface for Sample Weight Transfer

# Tablet Disintegration Tester



## Features

- Advanced microcontroller based user friendly, state-of-the-art product design with alphanumeric splash waterproof polyester soft keys. User interactive software in dialogue mode.
- Meets USP, EP, IP, ASTM, etc specifications
- Moulded Clear acrylic water bath with illumination for better visibility.
- Baskets are automatically lifted at the end of the test
- Capability for dual buffer disintegration tester

# Tablet Friability Tester



## Features

- Advanced microcontroller based user friendly, state-of-the-art product design with alphanumeric splash waterproof polyester soft keys. User interactive software in dialogue mode.
- Meets USP, EP, IP, BP, etc specifications
- User selectable Operating mode - Count or Time
- Automatic discharge of the tablets into individual sample tray after completion of each cycle
- 10° tilting of drums as per USP recommendation
- Easy front sample loading
- Supports friability drum & abrasion drum as well
- Calculation of Friability: Percentage Weight-Loss
- Balance Interface for online Sample Weight Transfer

# Common Features

- Error indication to trace out the problem
- GLP compliant report format with Alphanumeric entries of Sample name & ID No., other parameter, date for authentication
- Built-in Real Time Clock (RTC) on report printouts for authentication
- RS 232C Interface for PC connectivity & Parallel port for printer



## Hardness tester – TH 1050S



## Hardness tester – TH 1050M



### Single Station Features

- Advance Micro-controller based user-friendly, state-of-the-art product design with alphanumeric keyboard.
- Single Station Automatic measurement of tablet parameters - Diameter/Length & Hardness
- Wide Measurement Range and Units:  
Tablet Hardness upto 500N; (N, Kp, KgfSc, Pound)  
Tablet Diameter/Length upto 40 mm; (inch or mm) (60mm option available for bolus tablets)
- Automatic run can be performed continuously up to 1- 99 tablets. RUN can be re-started on power failure or on System Reset with last run parameters.
- Large Non-Volatile data storage memory: 99 methods, Users Result and Validation data
- Validation/Calibration protocol with verification for Hardness - 3 point Load Cell calibration with Standard weights and Diameter/Length Calibration with Standard gauges.
- GLP compliant print reports of Results, Program methods and Validation/Calibration data with built-in Parallel port printer interface.
- Two Tier - a) ADMIN, and b) USER password protection for method editing and Validation.
- Built in dual RS 232 C interface for data transfer for PC and Balance for Sample Tablet weight transfer.

### 12 Point Carousel Features

- Advance Micro-controller based user-friendly, state-of-the-art product design with Alphanumeric keyboard.
- 12 Position Carousel for Automatic measurement of tablet parameters-Width, Thickness, Diameter/Length & Hardness.
- Wide Measurement Range and Units:  
Tablet Hardness upto 500N; (N, Kp, KgfSc, Pound)  
Tablet Diameter/Length upto 32mm; inch or mm  
Tablet Thickness upto 15mm; inch or mm
- Automatic run can be performed continuously up to 1- 99 tablets. RUN can be re-started on power failure or on System Reset with last run parameters.
- Large Non-Volatile data storage memory: 99 methods, Users Result and Validation data
- The built in Sweeping blades cleans the tablet path for removal of broken pieces, debris and dust.
- Validation/Calibration protocol with verification for Hardness - 3 point Load Cell calibration with Standard weights, Width/Length/Diameter & 3 point Thickness Calibration with Standard thickness gauges.
- GLP compliant print reports of Results, Program methods & Validation/Calibration data with built-in Parallel port printer interface.
- Two Tier - a) ADMIN, and b) USER password protection for method editing and Validation.
- Built in dual RS 232 C interface for data transfer for PC & Balance for Sample Tablet weight transfer.





## Automatic Karl Fischer Titrator (KAFI<sup>+</sup>)



### Features

- Complies with USP/BP/JP/EP/IP/ASTM standards
- Quick interchangeable imported burette assemblies with intelligent recognition for its volume size- 5/10/25ml with NIST traceability
- On-line leak rate correction available
- Microcontroller based variable speed, magnetic stirrer with digital indication
- Storage capability of 50 methods
- Last 10 results can be stored & printed with all the required parameters
- GLP compliant report format with Alphanumeric entries of Sample name & ID No., Titration parameter, date for authentication
- Two-tier password facility (ADMIN & USER) to protect stored methods from any misuse or unwanted change
- PC Compatibility software & built in balance interface

## Automatic Titrator



### Features

- Performs all types of titrations- Acid-Base or Aqueous, Non Aqueous, Redox, Complexometric, Argentometric or Precipitation, KF Titration, Back Titration
- Complies with USP/BP/JP/EP/IP/ASTM standards
- Imported burette assemblies of various volume size- 5/10/25ml with NIST traceability
- Can be used as simple pH meter with display of pH, mV, Temperature value Vortex stirrer for homogenous stirring with specially designed glass propeller for total chemical inertness
- Storage capability of 50 methods
- GLP compliant report format with Alphanumeric entries of Sample name & ID No., Titration parameter, date for authentication
- Two-tier password facility (ADMIN & USER) to protect stored methods from any misuse or unwanted change
- PC Compatibility software & built in balance interface
- Quick & easy interchangeability from titration mode to karl fischer titration mode



## MR-VIS+



### Features

- Patented Technique - Change in the intensity of reflected light by the sample
- Determines melting range & melting point of various samples
- Compliant with USP melting range procedure as per Class 1A & EP method 2.2.60
- User selectable operating mode- Manual & Auto
- Most suitable for powdered white & colored samples, can also be used for decomposed samples as well as waxy & polymer samples
- Calibration Mode-Built in calibration facility for 2 point auto calibration with USP Standards
- GLP compliant printout with sample name, ID No., date, time, etc for authentication
- Graphical report of temperature v/s light units with indications for start of melting & end of melting
- User friendly software with 20 method storage
- Onscreen Parameter/Result Display facility (MR VIS+)

## Pico pH / Conductivity / TDS Meter



### Features

- Advanced microcontroller based user friendly, state-of-the-art product design with alphanumeric splash waterproof polyester soft keys. User interactive software in dialogue mode for ease of operation with protection against invalid entries
- Complies with USP & DIN Standards
- Non-Volatile memory storage of 40 readings for each mode (pH/ mV-pH meter & Conductivity/ TDS/ Salinity-Conductivity meter) with temperature in pre-selected GLP or Non-GLP format
- Temperature compensation by Pt.100 temperature sensor. Range 0-150 °C
- Calibration data & Stored readings are Password protected with date stamp for authentication with facility of calibration reminder alarm
- GLP Compliant Alphanumeric entries of Sample name & identification number for authentication.
- Built-in Real Time Clock (RTC) & customer name on report printouts for authentication
- RS 232C Interface for PC connectivity & Parallel port for printer
- **pH meter**- 3 point (isopotential) or 5 point (Linearly segmented) calibration available
- **Conductivity meter**- 0.1/1.0/10K cell constants available
- Combined pH & Conductivity instrument is also available





# LABINDIA

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