

Dissolution System



NEW

Dissolution System

PG Instruments – a leader in the development of first class scientific instruments – is pleased to introduce its brand new Dissolution System – PG Instruments DS 14000 - providing a reliable, state-of-the-art testing facility with advanced features.

Designed and developed for the Worldwide Pharmaceutical market, up to and beyond standards recommended and adhered to by international regulatory bodies, the new Dissolution System is the perfect laboratory apparatus for today, and the future needs of the Pharmaceutical Industry.

Standard Features

The system features advanced, user-friendly Micro-Processor Control, which comply with current USP, IP and EP specifications. It has a splash-proof keyboard, moulded water bath – enabling comparative studies – together with an in-built immersion pump.

The mono shaft design has easy changeover between Apparatus I & II, which eliminates routine height validation as per USP.

All paddles, baskets and vessels are laser marked with serial numbers for traceability. The tablet dispenser drops 12 doses in a single instance.

The conical shaped, low evaporation recovery lids reduce media loss during a long run. The integrated pre-centred lids require no manual removal or positioning, ensuring the automatic centring of vessels and precise positioning of

paddle/basket without any special tool, as per Pharmacopeia requirements.

The system also features easy placement and locking of vessels, allowing the vessels to simply slide into place, and once placed, the vessels do not float, even when empty. There is also the facility to monitor vessel temperature with an external RTD Temperature Sensor.

of power interruption. Reports can be obtained even after instrument reset and will show error indication for problem traceability.

The DS 14000 can be programmed by the user to automatically start operation at a predetermined time.

Software

PG DS 14000 is GLP compliant, with alphanumeric entries of sample name, sample number and identification number for authentication. It has a built-in Real Time Clock, a Daily Auto Incremented Run Number and factory entered Customer Name with instrument serial number on report printouts. It has non-volatile memory storage of 15 methods with parameters, together with validation software, validating Revolutions Per Minute, temperature, sampling volume and replenish volume.

It also features user interactive software in dialogue mode for ease of operation, together with multilevel password protection for method editing (10 users).

The dissolution run can be started with last run parameters, and the facility to view set parameters during run. The Auto Start facility can continue the dissolution analysis in the event

Regulatory Compliance

The new PG DS 14000 meets all requirements relating to validation, qualification and calibration.

Appropriate qualification documents can be supplied with the instrument.



Stirring shafts fitted with sample baskets.

Multi-channel sampling peristaltic pump.





Intelligent Sampling System

- ▶ The system has automated sampling as per Pharmacopeia specifications. Sampling tubes are lowered into the media only at the time of sampling and withdrawn immediately after, with no part of the assembly contributing motion, agitation or vibration to the process.
- ▶ Sampling tubes are accurately moved to the USP sampling position.
- ▶ 12 bowls temperature monitoring system automatically measures and records the temperature of individual vessels at specified sample points.

Sample Collection

- ▶ 12 x 6 x 2 sets of samples can be collected. For more sampling intervals, 24 x 6 collection trays are also available.
- ▶ Option of 1.5ml & 2ml HPLC vials available.
- ▶ Overhead design for electronic safety and failsafe operation.
- ▶ Sensor to locate accurate position of tray, with alarm facility for collection of sample.
- ▶ Uniquely designed vial to minimise SLS spills due to effervescent characteristics.
- ▶ Precision positioning of vials or test tube tray for easy changeover.

Peristaltic Pump or Syringe Pump

- ▶ Proven Peristaltic pump with click on cassette for volume accuracy.
- ▶ Fixed length pump windings with colour coded calibrated stops for sampling volume accuracy.
- ▶ Software controlled pump speed and calibration.
- ▶ Tygon pump windings for SLS compatibility.
- ▶ Pump with planetary drive to ensure accurate sampling.
- ▶ High repeatability on all channels.
- ▶ 24 actively driven stainless steel rollers.

Reports

Selectable Report Format, complies with GLP requirements. The report gives the Run No., set parameters and actual parameters during the dissolution process, together with a diagnostic functionality report to ensure accurate working of the system. There is printout of parameters such as Vessel Temperature, Paddle and Basket Speed at every sampling interval. A validation report showing temperature, RPM, sample volume and replenishing volume.

Specifications

DS 14000 Dissolution System

General

Control	Micro-Processor Controlled (advanced version of Micro-Processor)
Temperature Range	30°C to 40°C
Temperature Resolution	0.1°C
Temperature Control Accuracy	+/-0.1°C
Temperature Sensor	Pt-100 (RTD) Display: 40 x 2 line Back-Lit liquid crystal display (LCD)
Keyboard	Alphanumeric splash-proof polyester soft keys
Method Storage	15 programs with parameters
Data Storage:	Available with Non-Volatile memory
Water Bath	29 litres capacity with built-in water level sensor
Bath Circulation	Immersion Pump
Paddle/Basket Shaft Speed	Range 20 to 250 RPM +/- 1%
Sampling Time Selectivity	Fixed/Programmable (varying intervals)
Time Interval Selectivity	In steps of one minute
Sampling Volume Range	0.5 – 25.5 ml
Maximum Number of Intervals	30
Dissolution Process Time	1 minute – 720 hours.

Report Format

GLP & Pharmacopeia compliant
 Programme parameter report
 Evaluation Software including - Evaluation Program Parameter – Evaluation Report – Dissolution Profile

Output

Printer	Compatible for deskjet, inkjet and dot matrix printer
Options	PC Connectivity
Power	120-230 VAC +/- 10%, 50Hz. – 60Hz.

Environmental Operating Conditions

Operation	Laboratory and/or QC Environment
Temperature	Ambient to 45°C
Humidity	5 to 90% non-condensing
Dimensions	115 x 60 x 70.5 cms (WxDxH)
Weight	140kgs. Approx.

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The highly qualified and long experienced team at PG Instruments Ltd are recognised experts in electrochemistry and relevant technology. They have been developing and manufacturing analytical instruments for science for over a decade and have a worldwide recognised reputation for excellence in their field.