

Dissolution Test Apparatus

test method

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 standardized conditions of liquid / solid interface, temperature, and solvent composition.

dissolution test apparatus

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 Koehler Dissolution Apparatus provides state-of-the-art dissolution testing with advanced features, which supports USP 1, 2, 5 & 6. This product is designed on the basis of specifications recommended by international regulatory bodies and the future needs of the Pharmaceutical Industry.

standard features

- Advanced, Micro-Controller based
- User-friendly, complies with current USP, IP & EP specifications.
- Splash waterproof keyboard: Alphanumeric polyester soft keys for keyboard.
- Molded water bath with 6+2 (3+1 & 3+1) vessel configuration enables comparative studies.
- Built-in immersion pump for uniform water circulation with audible, low water level alarm with indication on display for safety.
- Mono shaft design with easy changeover between Apparatus I & II eliminates routine height validation as per USP.
- Tablet dispenser-drops 6 dosage forms at a single instance. (Optional)
- 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 (PT100)
- The Dissolution Tester meets all requirements relating to validation, qualification and calibration.
- Appropriate qualification documents (I.Q. / O.Q.) can be supplied with the instrument.



software

GLP Compliance: Alphanumeric 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 15 methods with parameters.

Protects Editing, Avoids invalid entries: User interactive software in dialogue mode for ease of operation with protection against invalid entries. Multilevel password protection for method editing (10 users)

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.

Dissolution Test Apparatus – Automatic

additional features

Features of the Automatic and Plus Dissolution Apparatus include: 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.

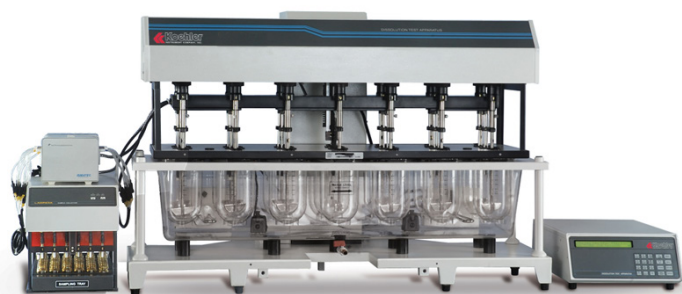
Ability to perform the dissolution test using two buffers (Buffer changing) for enteric coating tablets. Recovery Test facility to study 100% Drug Dissolution. Special software program for calculating % Drug dissolve v/s Time using individual tablet weight.

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. 6 vessel temperature monitoring system automatically measures and 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 vials tray is available.
- Over Head 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 minimize SLS spillover problem due to foaming characteristics
- Easy positioning with respect to vials or test tube tray for easy changeover



Automatic Dissolution Apparatus
with Peristaltic Pump

peristaltic pump - automatic

- 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.
- High repeatability on all Channels.
- 12 actively driven stainless steel rollers.



Automatic Dissolution Apparatus
with Piston Pump and Filter Changer

piston pump system - plus

- Microprocessor controlled and ideal for sample withdrawal from 6, 7, or 8 channels
- Eases filtration of sample before collection by using 0.22 & 0.45 μm Luer tip Syringe filters (fulfills the regulation of USP and other Pharmacopeias)
- Inert ceramic rotor overcomes 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 - plus

- Microprocessor controlled and designed to filter 6, 7, or 8 sampling lines simultaneously.
- Accessory for Inline Filtering of Sample before collection through Syringe Filters
- High Storage capacity – up to 96 filters at a time gives uninterrupted filtered sample collection for 16 Sampling Points.
- Used in conjunction with the Piston Pump for filtration down to 0.22 & 0.45 μm
- Individual channel sensors ensure filters are in place.
- If syringe filter is missing, automatic switch-over of valves to collect unfiltered sample, with an indication in the printout

Dissolution Test Apparatus

technical specifications

Display: 40 x 2 line back light liquid crystal display (LCD)
Water Bath: 17 L capacity with built-in water level sensor and front located drain tap for easy draining
Temperature Range: 30°C to 40°C
Temperature Resolution: 0.1°C
Temperature Control Accuracy: $\pm 0.1^\circ\text{C}$
Temperature Sensor: Pt-100 (RTD)
Paddle/Basket Shaft Speed: Range 20 to 250 RPM $\pm 1\%$
Dissolution Vessel: option for Polycarbonate / Glass vessels (clear, amber, peak vessels, 250, 150 & 100 ml dissolution vessels available)
Sampling Time Selectivity: Fixed/Programmable
Time Interval Selectivity: In steps of 1 minute
Maximum Number of Intervals: 30
Dissolution Process Time: 1 min. to 720 hours
Power: 110 / 220 V AC - 50 Hz / 60 Hz

Environmental Operating Conditions:

Operation: Indoor
Temperature: Ambient to 45°C
Humidity: 5 to 90% non-condensing.

Output:

Printer: Compatible for deskjet, inject and dot matrix printer with parallel port
RS232C: For PC Connectivity
21 CFR Part 11 compliance software available

Automatic and Plus Arrangements:

Sampling Volume Range: 0.5 - 25.5 ml
Replenishing mode selectivity: User selectable
Rinsing Functionality: Optional
Syringe Filter Capability (Plus ONLY)

included accessories - standard

SS Paddles
Baskets (USP Apparatus -1) with Mono Shaft
Glass Bowls
25mm Depth Balls
Cannula for Manual Sampling with Syringe
Special Tablet Dispensing Attachment for simultaneous dropping of tablets/capsules/pellets

included accessories - automatic units

Intelligent Sampling Manifold
Sample Collector with 72 position tray and 15 mL bottles
Teflon Carrier Tubing with Tubing Connectors
10 Micron Filters
Validation Software
Cleaning Software with Waste Tray and Beakers

ordering information

catalog no.	type of model	features	configuration	voltage
K90610	Basic	-	6+2	115V
K90611	Automatic	Peristaltic Pump	6+2	115V
K90612	Automatic	Piston Pump	6+2	115V
K90613	Automatic	Piston Pump & Filter Changer	6+2	115V
K90615	Basic	-	6+2	230V
K90616	Automatic	Peristaltic Pump	6+2	230V
K90617	Automatic	Piston Pump	6+2	230V
K90618	Automatic	Piston Pump & Filter Changer	6+2	230V
K90620	Basic	-	12+2	115V
K90621	Automatic	Peristaltic Pump	12+2	115V
K90622	Automatic	Piston Pump	12+2	115V
K90625	Basic	-	12+2	230V
K90626	Automatic	Peristaltic Pump	12+2	230V
K90627	Automatic	Piston Pump	12+2	230V

accessories

catalog no.	description
K90620-2	Sample Processor (Diluter / Dispenser)



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