PT-DT70

Low-Head Tablet Dissolution Test Instrument

The PT-DT70 is the low head flip back tablet dissolution testing instrument from Pharma Test. It provides a space saving, low cost entry into dissolution testing. Whether for a new laboratory or to meet tough budget requirements, the PT-DT70 offers a lot of instrument for a comparatively modest cost. The ideal instrument for all USP <711/724> and EP <2.9.3/4> applications for which automated and manual operation is required.

Tablet dissolution testing is one of the most important tests during development and manufacturing of solid dosage forms and Transdermals. Nearly all international pharmacopoeias describe a dissolution test instrument, in which at least 6 samples should be tested. The test vessel design, stirring speed range, temperature range and accuracy, stirrer design and relevant tolerances are specified.

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Today the instrument operator of such instruments expects not only conformity with the pharmacopoeia description, but also easy operation and accessibility to the test vessels. This means a dissolution bath should offer both good manual access as well as automation facilities. The PT-DT70 offers both. The test vessels are placed in 2 lines (4+3) and it is easy to remove samples and refill with solvent by lifting up the drive housing or use the sampling and tablet feeding holes in the top of the instrument. Special MDS-DT70 Manual Sampling Tools are available including disposable Syringes to make sure that the sampling position within the dissolution vessel is kept as per requirement in the USP/EP Guidelines.

The instrument design uses Mono-shaft Stirrer and Stirrer Adapters which avoid to re-adjust the Stirrer Immersion Depth after Tolling exchange. All stirrers USP/EP App. 1,2, 5 and 6 have the same total length. To insert samples and withdraw solution 7 holes and guiding tubes are placed inside the top cover of the instrument. Simply place your tablets next to the holes and introduce when ready for test start. For easy sampling use the PT-MDS Manual Sampling System which includes sampling tube - inline filter and a 10 ml. Disposable syringe. The clear-view U-shaped Plexiglas water bath offers excellent views of the samples while they are under test. Also the PT-DT70 is already equipped with all necessary interfaces to connect a sampling system for test automation. Interface for installation of a DATA-LOGGER PT-DL1 is built-in.

Operation Principle

Simply push the drive housing backwards. Free access to all vessels for filling or cleaning. The automated self-adjustment system of the vessels inside the water bath cover ensures correct positioning of the vessels with respect to the stirrer axis. All stirrers start simultaneously. The LED display will inform of the actual stirring speed and bath temperature. The stirrers will only rotate when the drive housing is in its operating position. For automated sampling the sampling probes placed into the corresponding holes inside the upper drive cover. They are constantly placed inside the dissolution vessels. They can be added at any time to the instrument each with its own filter. A computer controlled dissolution system will be able to control all instrument parameters and record the instrument output data. The PHARMA TEST tablet dissolution instruments can be used in compliance to apparatus 1, 2, 5 and 6 of the USP <711/724>and European Pharmacopoeia <2.9.3/4>.

Advantages

- 7 test stations = 1 additional unstirred vessel for blank or reference medium
- 4 + 3 format for USA FDA friendly application
- Pneumatic lift device which allows the drive head and testing tools to be raised out of the test vessels
- Internal Buzzer, programmable sampling information
- Housing made from stainless steel, top cover PP moulded
- Full USP <711/724> / EP <2.9.3/4> Pharmacopoeia conformity
- Mono-shaft Stirrers and Stirring Adapters fur USP/EP App. 1, 2 and 6 (Standard Supply Scope includes USP/EP App. 2 stainless steel Paddle Stirrer Adapters
- Fully adjustable and fully regulated paddle speed selection from 25 to 250 rpm
- Built in heater with microprocessor temperature control, over the range 25 to 45oC. Less than 0.3°C temperature deviation within the entire water bath
- Measurable Vibration Displacement: < 0.003 mm (if placed onto a suitable bench)
- LED display for target (user specified) and actual temperature
- Bi-directional RS 232C interface for control of:
  - thermostat
  - temperature
  - motor start / stop
  - speed functions
  - connect PT-DL1 Data Logger
- U-shaped Plexiglas (Perspex) water bath with cover for all 7 working positions. Auto centering system for all vessels. Heating of Dissolution Media in full compliance to the USP recommendation = no stirring while heating media to avoid air introduction!
- Delivery scope includes 7 round bottom test vessels
- Delivery scope includes a set of number stainless steel mono-shaft stirrers and paddle inserts
- Includes a locating gauge for setting stirrer depth and centering stirrer in vessel
- Adjustable lock-nuts for exact positioning of stirrer shafts inside the test vessels
- Built in calibration programs for speed and temperature

Features

- Fully USP <711/724> and EP <2.9.3/4> compliant
- 7 stirred positons
- Low head design with pneumatic flip-back lift
- Tablet drop directly through holes in instrument head
- Integrated calibration program for stirrer speed and temperature
- Options – Manual tablet magazine, PT-DL1 data logger
- Interfaces – RS232 to connect data logger and for remote control in automated applications, I/O port

Standard Scope of Supply

The PT-DT70 comes ready to use with the following standard scope of supply:

- One set of stainless steel paddles
- One set of batch coded 1000ml Borosilicate glass vessels
- One set of depth adjustment balls
- One bottle of ALGEX water preservative
- Comprehensive documentation folder including:
  - User manual
  - DQ/QC instrument compliance test certificate
  - IQ documentation
  - OQ documentation
  - Instrument logbook
  - Compliance certificates for vessels and stirring tools

Options

- Direct control of peripheral instruments via I/O port such as PTFC-2/8 fraction collector or DSR-M Sampling Robot
- 250 ml Mini Vessel set incl. mini paddle stirrers
- Amber colored vessels for UV sensitive test materials
- Full range of MonoShaft™ stirring tools available
- Full range of certified validation tools available
- PT-RP80 serial report printer

PT-RP80 Report Printer

Use the PT-RP80 serial report printer to print out the runtime report of the PTWS 120S.

Technical Specifications

Parameter	Specification
Display	LED Display for actual stirring speed and bath temperature
Data Entry	Functional and numerical keys
Acoustic Signal	Programmable acoustic signal for operator information
Interface	RS232 port
Stirrer wobble	within ± 0.2 mm
System tools:	Mono-shaft stirrer design, USP Apparatus 1,2,5, 6 tool adapter, cream cell, trans-dermal patch tools, each tool and vessel individually coded
Printer	External PT-RP80 report printer using long-life printer paper
Number of Stirred Vessels	6 (3 by 2 or 2 by 3 arrangement)
Standard Vessels	1 liter USP/EP Borosilicate glass vessel, each individually coded
Vessel Covers	Ultra-low evaporation design (< 0.7% within 24h)
Stirrer Speed	Adjustable within 20-250 rpm
Stirrer Shaft Wobble	Better than 0.2 mm total run out
System Tools	MonoShaft™ stirrer design, USP/EP apparatus 1, 2, 5, 6 tool adapter, cream cell, transdermal patch tools, each tool and vessel individually coded
Speed Accuracy	±2% of set speed, typically < 1%
Heater Range	25 - 45°C
Heater Accuracy	± 0.3°C inside the water bath
Calibration	Built-in calibration procedures for speed and temperature
Measurable vibration range	< 0.003 mm displacement at vessel - water bath cover interface
Bench Space Requirement	550 x 500 mm
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ paperwork included

We reserve the right to make technical changes without any prior notice.