

Low-Head Tablet Dissolution Test Apparatus - Type DT70



The **PT-DT70** is the low head **FLIP-BACK** Dissolution Tester 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.

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.

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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.

Brief Specifications:

- 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 for 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 45°C. 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:
 - a) thermostat,
 - b) temperature,
 - c) motor start / stop,
 - d) speed functions
 - e) connect PT-DL1 Data Logger
- U-shaped Plexiglas (Perspex) water bath with cover for all 7 working positions. Auto centring 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 centring stirrer in vessel.
- 7 adjustable lock-nuts for exact positioning of stirrer shafts inside the test vessels.

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- Built in calibration programs for speed and temperature.

Optional Equipment:

- PT-DL1 Data Logger, prints at programmable sequences, actual stirrer speed and bath temperature
- Fluor carbon coated Paddle stirrer adapters (USP App. 2)
- Stainless steel Basket adapters (USP App. 1)
- Stainless steel transdermal cylinder adapters (USP App. 6)
- Baskets in accordance to USP/EP apparatus 1, also gold plated with 10, 40, ob 100 mesh size
- Feloquine basket
- Amber coloured USP round bottom vessels (UV protection)
- Transdermal Cylinder (USP App. 6)
- Paddle over Disk (USP App. 5)
- Calibration Kit, includes optical speed meter, digital thermometer, wobble meter - all certified
- USP Reference Standard (RS) Tablets and Standards

How does the PT-DT70 operate ?

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>. The instrument

Automation:



PTFC2 Fraction Collector for automated Sampling

For automated fraction collection the PTFC2 Collector as well as a Peristaltic or Piston Pump can be added to the DT70. Sampling sequence timing, sampling volume and the optional media refilling process are programmed using the keypad of the PTFC2 instrument. In-situ sampling ferrules are placed into the DT70 through the top cover holes. Each ferrule holds a 5 or 10 μ PP Sinter Filter.

Technical Data DT70:

Number of Stirrers:	7
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
Bench Space:	L 55 x W 50 cm
Pre-heating time:	Approx. 30 mins.
Stirrer speed:	Adjustable within 20-250 rpm, accuracy ± 1 rpm
Bath Temperature:	Adjustable within 25°-45.0°C, accuracy $\pm 0.3^\circ\text{C}$
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
Vessel Centring:	Auto centring inside the bath cover
Calibration:	Built-in calibration procedures for speed and temperature
Measurable vibration range:	< 0.003 mm displacement at vessel - water bath cover interface
Certification:	All components certified to USP / EP requirements
CE / EMC Certification:	All CE / EMC Certification provided
Validation:	All IQ & OQ paperwork included

Automation:

- Using UV/VIS spectrophotometer with multiple-cell-changer. Interfacing via WinDiss32 Dissolution Software Program to most commonly available UV/VIS spectrometer types, like SA500 or Agilent 8453 Diode Array, or conventional UV/VIS monochromatic spectrophotometers, preferable double beam and scanning versions, like the T70, Cecil CE, Perkin Elmer Lambda etc.

Sampling System:

- PTFC-2 fraction collector can be connected. For the media transfer either a peristaltic or piston pump are used.

Weights and Packaging

Net weight:	48 kg
Gross weight:	73 kg
Packing .	760 mm x 650 mm x 750 mm

Pharma Test reserves the right to make technical changes without any prior notice.

Use the PT-DL1 to print the Runtime Log of the PT-DT70.



It includes the following information's:

- Programmed logging sequence
- Total number of logs
- Selected printing language
- Instrument serial number
- Firmware Release number
- Instrument status of heater (on/off), stirrer (on/off)
- Target bath temperature and stirrer speed setting
- Actual bath temperature and stirrer speed at each logging sequence

The PT-DL1 can be connected via the RS-232 interface at the PT-DT70 Dissolution Bath.

Automation incorporating the PT DT70



On-line Systems

This popular configuration is elaborate, but allows real time calculation of results using the WinDiss32 Dissolution Software and is by definition PC controlled.

With the SA500 Diode Array UV/VIS photometer, a multi-cell-changer (8 or 16 cells) and pump, the basic automation elements are entered into the program structure. This data, once installed will cause the software to further interrogate the user as to the configuration of the automation elements (wizard technology). Taking the spectrophotometer as an example, the program needs information as to whether there is a cuvette changer or not and if so, then is it a 6-, 8-way or 16-way. This is vital information as the blank medium has to be compared to the reference cell, and zeroed at the appropriate wavelength. In the case of the 6-cell changer this is done on cell 1 at the start of the measurement cycle only, whereas with an 8-way changer, the blank medium is normally selected to be transferred to cell 7, with the standard (for concentration calculation) in cell 8. This means that the medium can be compared to the reference cell and zeroed at the start of each measurement sequence. After the zero has been established the measurement sequence is then cell 8, followed by cells 1 to 6.

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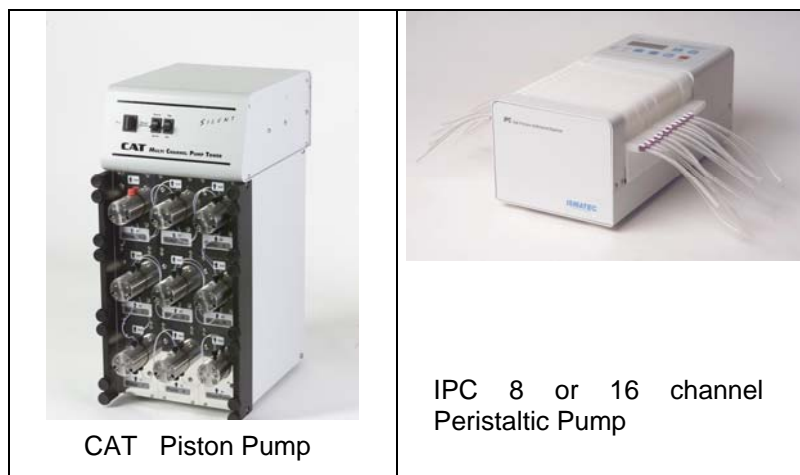
There are many spectrophotometer and auto sampler drivers available for connection to Pharma Test dissolution systems, even on-line HPLC, ask us..

Keeping the cost sensible....

We, at Pharma Test have opted to take the work out spectrometer selection and accessory hunting by offering complete systems which have not only differing degrees of sophistication but which also offer affordable options to cover all budgets.

Suitable Pumps

Peristaltic or Piston Pump



CAT Piston Pump

IPC 8 or 16 channel
Peristaltic Pump

Suitable Spectrophotometer with cell changers

UV/VIS Diode Array Types:

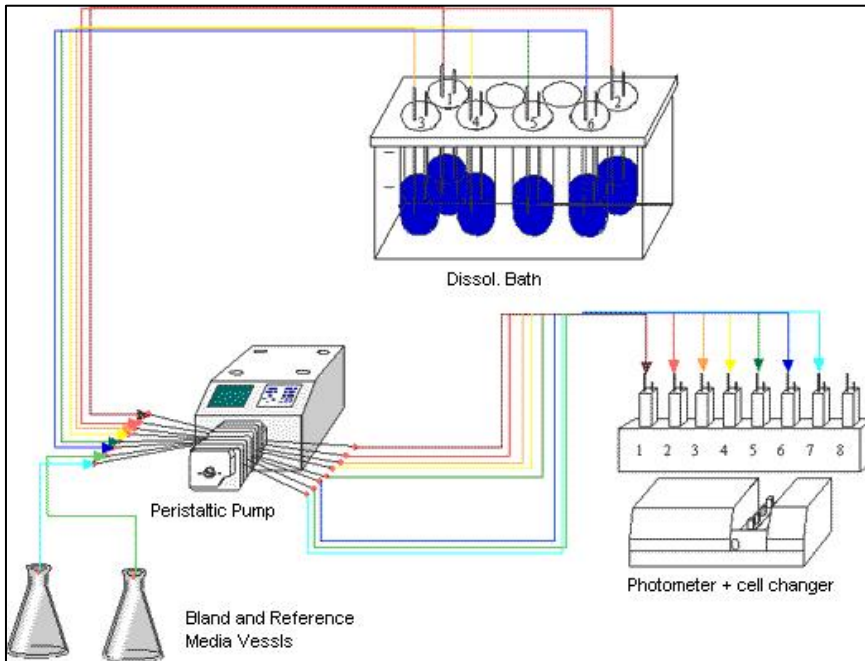
SA500 with 8-cell changer for 10x10mm and 20x10mm path length, or 16-cell-changer, fibre optic system

Agilent 8453 with 6- or 8-cell-changer

Monochromatic UV/VIS Spectrophotometer Types:

PTA T70 Split Beam Spectrophotometer and 8-cell changer, Cecil CE 3200 with 8-cell-changer, Jasco, Perkin Elmer Lambda, Shimadzu, Varian Carry 50, Analytik Jena Specord Series, Hitachi, Thermo Scientific, Beckman etc.

Automation: Principle of Operation



The operator describes the operational procedure within the wizard driven software. Then the system will flag when the samples have to be introduced; after this point, the dissolution system works automatically. Prior to the measuring time the pump will be started and circulate the solvent through a 5 or 10 micron filter. During a measurement the pump is stopped temporarily and data is read and stored by the PC. The same is repeated for any

programmed measuring cycle. As well as the measured absorbance, speed, temperature and pH-values (optional) are recorded. The selectable option to run a reference standard solvent, (which is measured in each cycle) or the entry of a theoretical maximum absorbance is available. Running a standard offers some advantages as results that may be influenced by a less than optimum light source, evaporation or temperature influences are corrected by the reference measurement. At the end of a run the operator creates his report and chooses which data that he needs to have printed. As all results remain filed within the system, a batch comparison statistical analysis can be performed at any time.

For further information about dissolution automation ask for our **WinDiss32** Dissolution software flyer or for demo version.

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