

Semi Automated Dissolution Test System - Type DFC-1210



A typical semi automated dissolution system **DFC-1210** is composed of a PTWS 1210 high-head, synchronous stirrer start Dissolution Bath with built-in printer, auto vessel centring bath cover, electrical drive head lift, full tubing installation in PTFE. For sampling the EPE auto sampling system in which the sampling tubes are only immersed inside the dissolution media while sampling only may be used and a manual Tablet Drop Magazine for synchronous tablet introduction. A Peristaltic or Piston Pump to withdraw the samples and a PTFC12 Fraction Collector. The PTWS 1210 uses in this application a synchronous stirrer start due to the installed tablet drop magazine. This is ideal for any automated operation as all samples are removed simultaneously too. The EPE auto sampling system operates similar to a manual sample withdrawal in which the sampling tube is only inside the dissolution media while the sample is removed. At the end of the sampling tube a 10 or 5 micron pre-filter is attached to avoid that non dissolved particles will be removed while sampling. Using the standard Method Filing System for the PTWS 1210 it is possible to enter all test description as a METHOD and file it on a USB memory stick. To start a test run simply call the valid Method, enter Batch number etc. and start.

Technical Data PTWS 1210:

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| Display: | LCD Digital Display (10 x 10 cm illuminated) for RPM, temperature, time, timer and pH (optional) functions |
| Keyboard: | Function and alpha-numeric keys |
| Method Filing: | USB memory stick for test description filing (method) |
| Interface: | 1 RS-232 port 1 TTL relay port to connect a PTFC 2 Fraction collector and a pump 1 pH-probe port |
| Printer: | Built-in Thermo Printer, prints test log as well as OQ information |
| Speed control: | adjustable from 20 rpm - 250 rpm |
| Accuracy: | ± 2% of set speed typically < 1% |
| Temperature control: | 750 W heater and pump system, protected against overheating and "no water" operation", adjustable from about 25°C - 50°C, water diffuser for even water distribution all over the bath |

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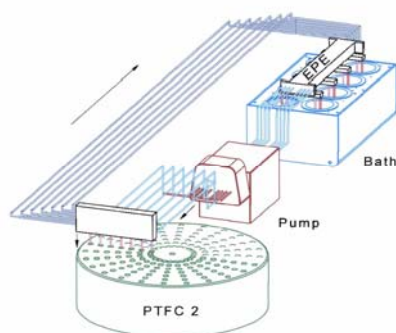
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|----------------------------|--|
| Accuracy: | ± 0.2° C inside the water bath |
| pH measurement * : | 0.05 - 9.00 |
| Accuracy: | ± 0.02 pH units |
| Number of stirred vessels: | 12 sample vessels and 2 (non stirred) for buffer and reference standard |
| Tablet Magazine: | Tablet drop magazine, covers all vessels for low evaporation |
| Heat-Up: | Energy saving, programmable, "auto start" heater function |
| Calibration: | built-in calibration procedures for speed, temperature control and pH-probe, OQ/PQ sequence programmable including alarm indicator |
| Stirrer wobble: | better than 0.2 mm |
| Vibration inside vessels: | Less than 0.00254 mm displacement |
| Vessel Centring: | auto centring inside the bath cover, easily aligned bath using centring tools and stainless steel support dish |
| Validation: | All IQ & OQ paperwork included |

Optional Equipment:

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|-----------|--|
| pH Probe: | measurement range 0.05 - 9.00 |
| Accuracy: | ± 0.02 pH units |
| ITM: | Media Temperature Monitoring System, measures the actual temperature inside of each Dissolution Vessel |

Automated Sampling...



The perception of automation in dissolution testing differs greatly from user to user. The most labour intensive stage is taking samples at the specified time periods as found in the company SOP (Standard Operating Procedure). This involves the removal of 6 samples according to the USP/EP and most other Pharmacopoeia, there is often a requirement for a fast or parallel start in most cases so that accurately timed sampling may be achieved. At this point the operator must also consider either replacing the collected samples volumes in the dissolution vessels or keeping an accurate record of the volumes taken from each vessel so as to be able to calculate the true concentrations

of subsequent samples.

The pumps available are either peristaltic, piston, or syringe based. The piston pump CAT12 will give first class accuracy in terms of volume removed from the system when samples are taken. Although the quality of the peristaltic pumps available today has vastly improved, it must be stressed that the pump is still working with flexible tubing and this should be qualified at the start of each determination in order to make sure that the flow rates are identical for each channel and that the tubing itself is in overall good condition and likely to last the duration of the procedure. A good tip for long tubing life is to always release the pressure rollers from the tubing either overnight or whenever the system is left for extended periods of time and not in use.

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Peristaltic Pumps....



The IPC16 series pumps are an alternative to the Watson-Marlow pumps and the IPC series allows a reasonable cost alternative for prolonged use. Again, if the laboratory standard is a Watson Marlow, or Ismatec we can provide the necessary control for sample transfer using this type of pump for standard off line systems (with Fraction Collector PTFC12 and reverse liquid flow feature).

Ismatec IPC is a flat bed design with all pump tubing laid out in front of the pump drive. The easy release individual cassette system offers some advantages for easy service. Again we can offer control from pump by the PTFC12 Fraction Collector.

Technical Data IPC16/24:

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| Number of pump channels: | 16 channels, pressure adjustable (IPC 24 channels as refilling option) |
| Rotation Speed: (diameter) | continuously adjustable, volume depends on tube size used |
| Sampling Accuracy: | ± 5 % |
| Speed: | adjustable 2.5 - 50 rpm |
| Tubing: | Ismaprene, Tygon, Silicone |
| Interface: | Signal I/O port - RS232 Analogue stop / start / reverse |

Dimensions and Weights:

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|---------------|---------------------|
| Net weight: | ca. 7 kg |
| Gross weight: | ca. 10 kg |
| Packaging: | ca. 60 x 30 x 30 cm |

CAT12 Piston Pump...



Pharma Test CAT12 multiple Piston Pump Unit offers a more accurate solution to sample removal and transfer. Exact volumes may be transferred from the sample vessels to a fraction collector such as the PTFC12 which needs actually 1 off CAT12 Pumps and 2 if media refilling is required. In this way, as vessel refilling is not used, exact volumes of sample removal can be recorded for subsequent concentration calculations. This system offers a more secure sampling method for non closed loop systems where the volume removed is calculated from an apparent flow rate over a fixed time period (as with peristaltic pumps). This system is not dependent on pump tubing quality and is also a good alternative when active materials are known to absorb on tubing materials such as Tygon or Silicone.

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Technical Data CAT12 :

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|--------------------|--|
| Number of Pistons: | 12 (2 CAT12 pumps are needed to withdraw and re-fill samples of a PTWS1210 or PTWS D610) |
| Minimum Flow Rate: | 0.15 ml/min |
| Maximum Flow Rate: | 20.0 ml/min |
| Accuracy: | < 1% over the full range |
| Tubing: | 1.0 mm ID - 1.6 mm OD FEP or PTFE (not included in supply scope) |
| Interface: | 1 RS-232 port 1 Analogue signal I/O port |

Dimensions and Weights:

| | |
|---------------|--------------------|
| Net weight: | ca. 12 kg |
| Gross weight: | ca. 19 kg |
| Packaging: | ca 60 x 50 x 50 cm |

PTFC12, Fraction Collector...



Directly connected to a PTWS1210 or any dissolution bath. Whenever automated sampling is required the PTFC12 fraction collector together with a pump offers an ideal choice. The control of the fraction collector in regards to sampling times, dosage volumes, refilling and pump drive is done via the keypad of the PTWS1210 Dissolution Bath or by calling the relevant filed testing Method. A method includes sampling time, interval sequence and number of samplings (up to 20), product descriptive data. Connect the system tubing together for an automated operation.

Correctly positioned sampling tubes while the EPE is immersed into the media, equal sampling times and standardized solvent transport offer a high standard of reproducibility and reliability for dissolution tests. Also the economical aspect will show that automated sampling offers advantages as the operator does only need to fill the flasks and introduce the samples, thereafter the system operates automatically. Using a PTFC12 fraction collector means that the way of analysis is open for spectrometer or LC. The filled vials within the vial dish are manually moved to the analyser and either manually injected or transferred to an auto injection system.

As the PTFC12 is equipped with a RS-232 interface, it can be linked into an on-line dissolution system in front of the photometer cell changer. In this configuration the samples can either be collected into the PTFC12 vials or measured online while the instrument control is done by a PC and software.

A multi-channel peristaltic pump like the IPC16 with flexible pump tubing is mostly used for solvent transportation. If drug absorbance is a problem the use of the CAT12 piston pump and PTFE tubing is possible, too. Both pumps are controlled by the PTFC12 for start/stop and reverse operation. To sample from 12 + 1 vessel also refilling is possible when the optional available refilling valve system E-VEN is inserted and a suitable pump IPC24 is connected, maximum 20 samplings can be done

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Technical Data PTFC12:

| | |
|-------------------------------|--|
| Display: | LED Display |
| Keyboard: | numerical and function keys |
| Number of sampling positions: | 10 for each 6 vessels |
| Total Number of vials: | 140 |
| Standard Vial Size: | 12x75 mm - approx. 5ml vol. (other sizes available) |
| Standard Sampling volume: | selectable within 1 - 20 ml (depends on vial size used) |
| Accuracy: | using peristaltic pumps approx. \pm 5% using CAT8 piston pump better \pm 1% |
| Interface: | 1 RS-232 port 2 TTL ports |
| Sampling time: | selectable from 2 min. to 10 hours |
| Media Refilling: | optional using E-VEN and 24 channel peristaltic pump |

Dimensions and Weights:

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|---------------|-------------------------|
| Net weight: | approx. 8 kg |
| Gross weight: | approx. 13 kg |
| Packaging: | approx. 50 x 50 x 50 cm |

A typical system consists of:

- 1 PTWS 1210 dissolution bath equipped with paddle mono-shaft stirrers, aothers available, including Method filing system
- 1 EPE Auto Sampling system with 12 sampling tubes and PP Filters
- 1 ITM Media Temperature Measuring System (optional device)
- 1 Manual Tablet Magazine and auto vessel centring and sealing covers
- 1 Built-in Printer, prints Test Report at the end of a run
- 6 Depth setting balls 25 mm OD
- 1 Inert PTFE tubing installation set
- 1 IPC16 multi-channel peristaltic pump (no refilling) or IPC24 pump (with refilling- requires E-VEN refilling valve set for PTFC12, too)
- 1 PTFC12 fraction collector and 140 vials

Principle of Operation...

As soon as the samples have been inserted the system will start its automated operation. The sampling times had been programmed at the keyboard of the PTWS 1210 Dissolution Bath. After start of test a command is send from the Dissolution Bath to the Fraction Collector and from there to the connected Pump to start a sampling sequence. As sampling tubes and filter tips are already immersed into the media the pump will be started to fill up the tubing, while the solvent circulates in a closed loop within the vessels and the pinch valves inside the PTFC12. When all tubing is filled-up the pinch valves are switched to open the dosage tube line and the samples are collected into vials inside the collector dish. Depending on the system configuration after dosing the volume will be refilled. At the end of a cycle all tubing is empty. The system is waiting for the next sampling time. All vials are covered during the test, the vial dish can be easily removed. Also special dishes are available for HPLC vials.

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The WinPTFC32 CFR21 Part11 compliant software

The CFR 21 Part 11 compliant WinPTFC32 software can be applied on-line to allow the control of a peristaltic or syringe pump as well as the PTFC12 Fraction Collector. It will record all instrument parameters, such as stirrer speed, bath temperature, sampling times, and refilling timing. At the end of a run a printed Run Time Log and Audit trail are available. For more information see also the description of the WinDiss32 Software suite.

The WIN-PTFC software (not CFR compliant):

The WIN-PTFC software can be applied on-line to allow the control of a peristaltic or syringe pump as well as the PTFC12 Fraction Collector. It will record all instrument parameters, such as stirrer speed, bath temperature, sampling times, and refilling timing. At the end of a run a printed Run Time Log is available, also adsorbance data may be manually entered to use the powerful result presentation of the WIN-PTFC software. The Calculations are made based relative to the theoretical maximum absorbance for 100% dissolved active.

PC Installation Requirement:

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|------------------------|--|
| Hardware requirements: | up-to-date PC system incl. CD drive, monitor, keyboard, printer |
| COM Ports: | 2 RS-232 COM Ports to connect Dissol. Tester and PTFC12 1 Printer Port |
| Operating System: | Windows® 2000, XP (GB or US version) |
| 21CFR Part 11: | Password Protection for Method development No test data collection or calculation in this program |

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