

Semi Automated Dissolution Test System - Type DFC-100



A typical semi automated dissolution system **DFC-100** is composed of a PTWS100 staggered stirrer start Dissolution Bath with built-in auto vessel centring and sealing cover, full tubing installation in PTFE (P) including in-situ sampling tubes, Peristaltic or Piston Pump, and a PTFE2 Fraction Collector. Even so the PTWS100 offers the staggered stirrer start option all can be started parallel which is required for automated operation..

In this configuration the sampling tubes are always immersed into the media. This procedure is widely used and has been introduced more than 20 years ago.

Technical Data PTWS100

| | |
|----------------------------|---|
| Tool Speed Range: | 20 – 220 RPM |
| Accuracy: | < 1% |
| Heater Range: | 25 - 45°C |
| Accuracy: | ± 0.2°C |
| Tool positions: | 6 |
| Acoustic Signal: | programmable acoustic signal for operator information |
| Sampling: | stainless steel sample probes, remain inside the vessels, include inline Filter-Tip |
| Tablet Drop: | manual through the hole inside the covers (no magazine) |
| Method Filing: | Method filing system included in standard supply scope, no external memory required |
| Voltage requirements: | 230V 50Hz |
| System tools: | mono-shaft stirrer design includes USP Apparatus 1, 2, 5 (3 variants), and 6, cream cell, trans-dermal patch tools - each tool individually coded |
| Stirrer Start: | Synchronous stirrer start, all stirrers are in operating position |
| Tool height qualification: | tool depth gauges (balls) included in supply scope |
| Heater system: | external heating system including pump, 750W heater with thermal protection |
| Thermal protection: | 1 over-temperature cut out, 2 thermal fuses |

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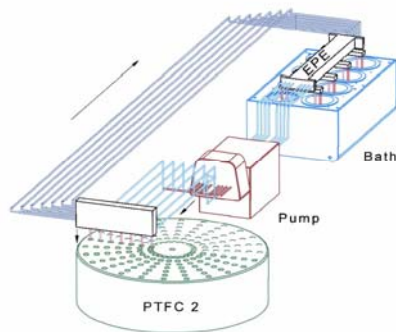


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|-------------------------|--|
| Power electronics: | all power electronic control boards inside the heater system, easy access without to move the qualified dissolution bath |
| Water circulation: | water circulated through special diffuser system, flow detector for pump security, no water no heater and no pump |
| Water Bath design: | single piece blow moulded with PP cover, easy removable for cleaning, also 2 litre bath and vessels available |
| Test Vessels: | 1 litre USP Borosilicate vessels supplied with individual number coding |
| Certification: | all components certified to USP / EP requirements |
| CE / EMC Certification: | all CE / EMC Certification provided |
| IQ / OQ : | all paperwork for system qualification provided with instrument |
| Instrument Log: | log is printable on external data logger DL1 |
| Vibration: | bath and pump system on vibration-free mounts. |
| Measurable vibration: | Less than 0.003 mm displacement |

Bench Space: 45 x 65 cm (2 by 3) or 65 x 45 cm (3 by 2)

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 valve-less piston pump CAT8 or 12 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 IPC8 or 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 PTFC2 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 PTFC2 Fraction Collector.

Technical Data IPC:

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|--------------------------|--|
| Number of pump channels: | 8 or 16 channels, pressure adjustable (IPC 16 channels) |
| Rotation Speed: | continuously adjustable, volume depends on tube size (diameter) used |
| Sampling Accuracy: | ± 5 % |
| Speed: | adjustable 2.5 - 50 rpm |
| Tubing: | Ismaprene, Silicone or other |
| Interface: | Signal I/O port - RS232 Analogue stop / start / reverse |

Dimensions and Weights:

| | |
|---------------|---------------------|
| Net weight: | ca. 3.5 kg |
| Gross weight: | ca. 8 kg |
| Packaging: | ca. 40 x 30 x 30 cm |

CAT valve-less Piston Pump...



Pharma Test CAT 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 PTFC2. 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. The CAT pump is available with 8 or 12 pump heads, also for auto media refilling

Technical Data CAT8:

| | |
|--------------------|---------|
| Number of Pistons: | 8 or 12 |
|--------------------|---------|

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| 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 |

PTFC2, Fraction Collector...



Directly connected to the PTWS100 or any dissolution bath. Whenever automated sampling is required the PTFC2 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 Dissolution Bath. Enter sampling time, interval sequence and number of samplings (up to 20). Connect the system tubing together for an automated operation.

Correctly positioned sampling tubes while 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 PTFC2 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 PTFC2 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 PTFC2 vials or measured online while the instrument control is done by a PC and software.

A multi-channel peristaltic pump like the IPC8 with flexible pump tubing, like Ismaprene, is mostly used for solvent transportation. If drug absorbance is a problem the use of the CAT piston pump and PTFE tubing is possible, too. Both pumps are controlled by the PTFC2 for start/stop and reverse operation. To sample from 6 + 1 vessel also refilling is possible when the optional available refilling valve system E-VEN is inserted and a suitable pump IPC16 or CAT12 is connected, maximum 20 samplings can be done.

Technical Data PTFC2:

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|-------------------------------|-----------------------------|
| Display: | LED Display |
| Keyboard: | numerical and function keys |
| Number of sampling positions: | 20 |

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| 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 16 channel peristaltic pump |

Dimensions and Weights:

| | |
|---------------|-------------------------|
| Net weight: | approx. 6 kg |
| Gross weight: | approx. 11 kg |
| Packaging: | approx. 50 x 50 x 50 cm |

A typical system consists of:

- 1 PTWS 100 dissolution bath equipped with paddle mono-shaft stirrers (others available)
- 1 set of ANSI 316 stainless steel sampling probes, PP filters 10 micron (5 micron option)
- 6 depth setting balls 25 mm OD
- 1 inert PTFE tubing installation set
- 1 IPC8 multi-channel peristaltic pump (no refilling) or IPC16 pump (with refilling- requires E-VEN refilling valve set for PTFC2, too)
- 1 PTFC2 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 PTWS100 Dissolution Bath and are filed for consequent tests. 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 PTFC2. 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 of the PTFC2. Depending on the system configuration after dosing the volume will be refilled. At the end of a cycle all tubing is emptied. 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.



Data Logger...

To report the actual system parameters, like speed, temperature, time and may be printed using the PT-DL1 thermo printer.

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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 PTFC-2 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.

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 PTFC2 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