



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 taking of 6 samples according to the USP 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...



The pumps available are either peristaltic or valve-less piston pump based. The piston pump CAT8 or CAT12 (for auto media refilling) 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.

Whenever automated sampling is required the PTFC system together with CAT8 or CAT12 valve-less piston 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 PTFC2 keyboard and Display or directly from the connected PHARMA TEST Dissolution Bath. Enter up to 20

Fraction Collector - Type PTFC

different sampling sequences with the same time delay and connect the system tubing and pump together for a automated operation.

Connecting a PTFC system to a PTWS 100/600/610/310 or a PTFC12 to a PTWSD610/1210 series Dissolution Bath offers programming of any sampling time up to 20 (10) sequences. You do have another branch bath, the DT7/70 instrument, no problem, use the PTFC2 keyboard and enter your sampling sequence but in equal intervals, like 10 - 20 - 30 minutes.

The tubing connection should be made of PTFE, FEP or similar, we offer them ready to install to any of our baths.

PTFC2 System: a bit more simple and money saving...



Instead of using the CAT valve-less piston pump, a multi-channel peristaltic pump IPC8 (or IPC16 for auto media refilling) with flexible pump tubing is used for solvent transportation. Of course also this pump is 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 is inserted and a suitable pump. IPC16 is connected, maximum 20

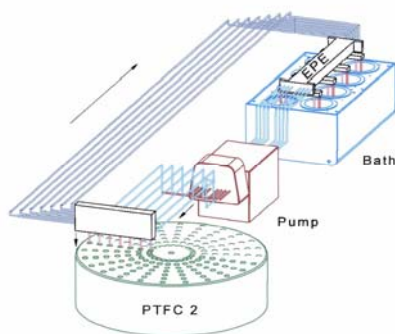
samplings can be done.

Automated sampling offers...

Correctly positioned sampling tubes while in-situ immersed into the media only while sampling, (only if the PTWS310, PTWS600/610/1200/1210/D610 are used), 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.

Operation Principle

As soon as the samples have been inserted the system will start its automated operation.



The sampling times had been programmed either at the keyboard of the PTA dissolution bath or at the PTFC2 Fraction Collector. After start of test a command signal is send from Fraction Collector to start the pump. Now the pump will start to fill up the tubing, while the solvent circulates therein. When all tubing is filled-up the dosage tube line is opened and the samples are collected in the vials inside the collector dish. Depending on the system configuration after dosing the volume will be refilled back into the vessels using fresh buffer. 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 LC vials

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Technical Data PTFC 2:

Display:	LED Display
Keyboard:	numerical and function keys
Number of sampling positions:	20 (PTFC12 2x10)
Total Number of vials:	140
Standard Vial Size:	12x75 mm - approx. 5ml vol.
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

Pumps :

The IPC8 or IPC16 series peristaltic pumps are an alternative to the Watson Marlow pumps. The easy release individual steel cassette system offers some advantages for easy service, so does the screw adjustment facility to correct dosing volume precision for each channel. Again, if the laboratory standard is a Watson Marlow, or Ismatec we can provide the necessary control cable for sample transfer using this type of pump for standard off line systems (with Fraction Collector PTFC2)

Technical Data IPC Peristaltic Pump:

Number of pump channels:	8, 16, or 24 channels, pressure adjustable (IPC16 = 16 channels, IPC24 = 24 channels for 12 vessel instruments)
Rotation Speed:	continuously adjustable, volume depends on tube OD used
Sampling Accuracy:	$\pm 5\%$
Speed:	adjustable 2.5 - 50 rpm
Tubing:	Ismaprene, Silicone and other
Interface:	Signal I/O port - 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 8 or 12 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, if 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). The CAT piston pump 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. Its usually supplied with either PTFE or FEP tubing installation. The pump is supplied with 8 or 12 working channels and a separate channel for rinsing or flushing. Each position contains a miniaturised precision pump element which ensures reliability and accurate sample delivery on each of the working channels. The valve-less micro-piston pumps are made of ceramic and therefore highly inert for all types of common dissolution media. The rinse pump is invaluable in keeping the system clear of crystallising material especially when using buffered media. This pump can operate as a stand alone device (contact closure) or be controlled by either the PTFC2 Fraction Collector directly or by dissolution software WinPTFC32. The sample volumes are removed with great accuracy (<1%) and excellent precision (<0.5%).

Technical Data:

Number of Pistons:	8 or 12
Minimum Flow Rate:	0.15 ml/min
Maximum Flow Rate:	20.0 ml/min
Accuracy:	< 1% over the full range
Materials used:	all wet part: 99.7% Al ₂ O ₃ , Teflon or PEEK
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

Typical System Configuration PTFC without media refilling - CAT pump

- 1 PTFC2 Fraction Collector incl. standard vial dish
- 1 CAT 8 Piston Pump, 8-channels + 1 cleaning channel (without media refilling)
- 1 set of PP Sinter filters 10 or 5 micron

Typical System Configuration PTFC without media refilling - Peristaltic Pump

- 1 PTFC2 Fraction Collector incl. standard vial dish
- 1 IPC 8 Ismatec 8-channel peristaltic pump (without media refilling)
- 1 set of Ismaprene Pump Tubing
- 1 set of PP Sinter filters 10 ob 5 micron

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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 PTFC2/12 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 please see also 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 PTFC2/12 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:

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 PTFC2/12 1 Printer Port
Operating System:	Windows® 2000, XP (GB or US version)
21CFR Part 11:	Password Protection for Method development (WIN-PTFC) No test data collection or calculation in this program

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