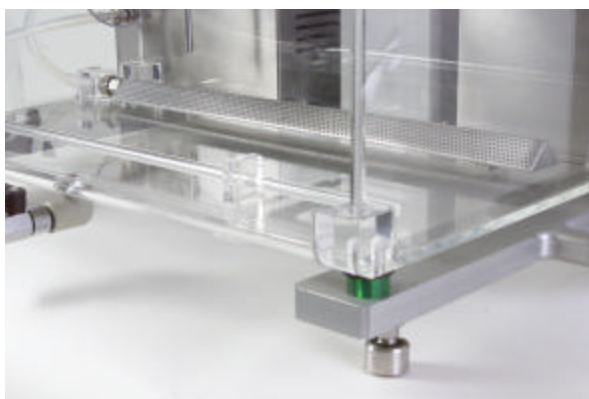




PTWS 310, compact - complete - all-in-one design affords easy and safe handling for correct tool height and sampling positions – unique instrument design and handling security.

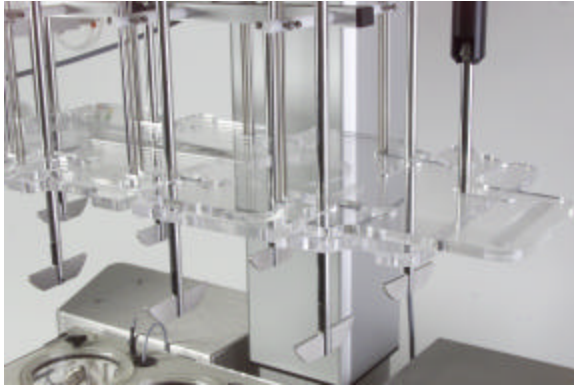
Tablet dissolution testing is one of the most important tests during development and manufacturing of solid dosage forms and transdermals. Nearly all international pharmacopoeias describe a dissolution test instrument, in which at least 6 samples should be tested. The test vessel design, stirring speed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

Today the instrument operator of such an instrument 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 PTWS 310** offers both.



All test vessels are placed in 4+4 rows and it is easy to remove spent samples and refill with solvent. The clear-view plexiglass water bath and the central drainage tap make sure that the bath can be cleaned any time should this be required. The solid design of the bath and the same clearance of the bath frame to any of the vessels inside it, ensures a perfect temperature distribution throughout. A built-in water diffuser distributes the heated media inside the bath. The bath itself rests on vibration absorbers. This avoids any vibration transfer from either inside the instrument or even from external equipment placed on the same bench surface.

Dissolution Testing – PTWS 310



The PTWS 310 can be equipped with an EPE-C auto sampling manifold system. Its equipped as standard with a manual tablet synchronous drop magazine which inserts all samples at the same time whenever the test conditions are in the valid operational range (temperature / speed). An automated motor driven magazine is available as an option.

pH values before and after a test.

If the EPE C sampling system is attached the PTWS 310 can be equipped with the ITM-C external temperature probes to record both bath and individual vessel temperature as well as a pH-probe to measure

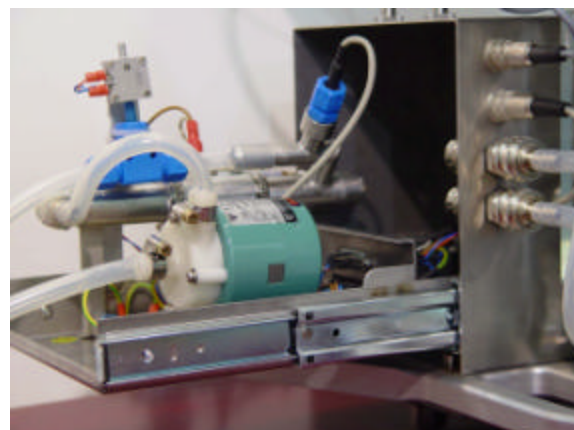
The new mono-shaft™ design means you only change the stirrer inserts. The shafts are simply placed into the drive system, calibrated once and then remain there with no need for further adjustment. Regardless of tool choice, the head can be moved up so as to allow easy removal of the test vessels from the bath.



placed into the drive system, calibrated once and then remain there with no need for further adjustment. Regardless of tool choice, the head can be moved up so as to allow easy removal of the test vessels from the bath.

This illustration shows the shafts equipped with stainless steel paddle blades. A total of 8 immersion positions operate within the PTWS 310 system. All 8 of these are for stirring tools. Another unique labour-saving design feature is the easy access pump and heating system as well as the power connection. Both are located at either side of the instrument. This means that there is no need to move the bath from its position should the instrument

need to be qualified or maintained.



Within the pump housing unit, the built-in circulation pump is spring loaded for totally vibration-free operation. The measurable vibration is even lower than those systems which use a separate heating system placed to the same bench. Incorrect settings of the bath are monitored, a warning is displayed if the temperature or speed is outside the target settings or even the water level is too low.

The traffic light information centre clearly shows the operator the status of the instrument, running well = green light - slight problem = yellow or out of specification = red. All this is automatically logged; the log file can be printed any time using the built-in thermo printer.

The new PHARMA TEST PTWS 310 tablet dissolution tester exceeds all technical requirements which are required by USP, FDA, Europ. and German Pharamcopoeias.

The PTWS 310 Tablet Dissolution Instrument offers:

- Instrument suitability test prior to any test start or during a run: SST test.
- Auto-control to ensure correct water level, tool speed and bath temperature.
- Vertical and horizontal adjustment facilities of waterbath, vessels, and stirrer drive.
- Waterbath placed on vibration absorbers and spring loaded assembly of pump to ensure vibration free dissolution testing.
- Clear LCD screen to display actual operational status; traffic light information to highlight any errors.



- Visible and acoustic alert informs the user of any action which should be taken with the instrument.
 - Fully automated self check and re-adjustment of stirrer drive and bath thermostat as soon as any change has been detected.
 - Programmable heater start and stop time: saves energy.
 - Electronically controlled central drive system lifting device.
- Easy access to all 8 test vessels.
 - Optional EPE-C auto sampling manifold system.
 - Manual Tablet Magazine and vessel cover as standard supply.
 - Automated or manual synchronous drop tablet magazine.
 - Very short pre-heating time and narrow temperature accuracy limits of temperature control due to new stainless steel vibration free waterbath diffusor jet.
 - Additional vessels to take either reference standard or blank media.
 - Built-in instrument log; files all changes and calibration data during duty cycle time of the instrument: prints content onto the built-in printer.
 - Calibration menu for stirrer speed, bath temperature, pH-probe.
 - RS-232 interface for full externally controlled operation and instrument data transfer.
 - Optional pH-probe to read pH value of each vessel prior to and after a test run.
 - Manual temperature sensor probe to read temperature of each vessel prior to and after a run; during operation the probe is placed into the reference vessel for continuous monitoring.
 - Optional "ITM-C" individual temperature measurement device can be attached to the EPE-C auto sampling system: monitors temperature of medium in each vessel.
 - OQ/PQ auto information, performance sequence programmable.
 - Instrument housing made out of stainless steel, always clean, GLP conforming.

Simply press a key to move the instrument's drive housing upwards. Free access to all vessels for filling or cleaning. The automated self-adjustment system of the vessels inside the waterbath cover ensures correct positioning of the vessels with respect to the stirrer axis. Each stirrer can be individually removed from the vessel enabling runs to be started in the sequence of sampling handling.

The instrument detects any incorrectly inserted stirrer and sends an alarm. The big LCD screen will inform which fault has been detected while the information automatically is filed in the instrument's log.

The correct positioning of the bath and vessels is also controlled; any change in the correct position will trigger an alarm and ask the use to take action. This is to ensure that even after laboratory cleaning, the instrument is correctly set-up.



Red - yellow - and green "traffic" lights inform the user from anywhere in the laboratory of the instrument's status. Yellow will light up if any specification is slightly outside the limits but with no major problem for the correct performance of the dissolution run. The red light comes on as soon as any critical fault has been found which would surely question the validity results of test results, such as incorrect stirrer position etc.

For automated sampling the "EPE-C" electrical sampling probe manifold may be used. It can be added at any time to the instrument. 8 stainless steel sampling probes, each with its own filter, are moved into the media for the sampling time duration and removed after. They may also stay inside the vessels during the entire test, if the users prefers to do so. 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 and Europ. Pharmacopoeia. The instrument is available as a 2 ltr. version too.

Technical Data:

Display:	LCD Digital Display (10 x 10 cm illuminated) for RPM, temperature, time, timer and pH (optional) functions
Keyboard:	Function and alpha-numeric keys
Interface:	1 RS-232 port 1 TTL relay port to connect a PTFE 2 Fraction collector and a pump 1 pH-probe port
Printer:	Built-in Thermo Printer, prints test log as well as OQ informations
Speed control:	adjustable from 20 rpm - 250 rpm
Accuracy:	± 2% of set speed typically < 1%
Temperature control:	1000 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
Accuracy:	± 0.2° C inside the water bath
pH measurement * :	0.05 - 9.00
Accuracy:	± 0.02 pH units
Number of stirred vessels:	8 vessels for buffer / medium
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 0.3 mm/s @ 50 Hz
Vessel Centring:	auto centring inside the bath cover, easily aligned bath using centring tools and stainless steel support dish
Evaporation Covers:	provided for all vessels with suitable tool / sampling tube cut outs
Validation:	All IQ & OQ paperwork included

Options:

Temperature Monitoring:

- EPE-C auto sampling system in connection with either manual or automated tablet magazine including low evaporation vessel covering
- ITM-C individual vessel temperature monitoring in connection with EPE-C system available

Automation:

- using UV/VIS spectrophotometer with multiple-cell-changer. Interfacing via WINDISS 32 Dissolution Software Program to most commonly available UV/VIS spectrometer types, like **SA500** or **Agilent 8453** Diode Array, or conventional UV/VIS spectrophotometers, preferable double beam and scanning versions
- RS-232 Driver Software to control the instrument using Agilent Chemstation™ Software (dissolution package)

Sampling System:

- sample fractions using the PTFE 2 fraction collector and either a peristaltic or piston pump. All controlled by the PTWS 310 built-in electronics - no software required !

Others:

- pH-probe for online reporting the pH of the buffer or medium in one of the extra vessels
- Built-in data logger to track stirrer speed, vessel and bath temperature, pH value
- Stirrer Inserts in accordance to USP/EP apparatus 1, 2, 5 and 6
- Capsule Sinkers in acc. to the Japan. Pharmacopoeia and others
- Amber coloured vessels (UV protection)
- Suppository dialysis cell PTWS 0 for suppository dissolution testing
- Baskets in accordance to USP/EP apparatus 1, also gold plated with 10, 40 or 100 mesh sizes
- IDP, Intrinsic dissolution tools
- Paddle over disc options
- Trans-dermal patch tool option
- Ointment tool option
- Sampling manifold (filtered), PT-MDS
- Calibration kit, includes optical tachometer, digital thermometer, wobble meter - all certified
- USP calibrator tablets and standards

Dimensions and Weights:

Net weight: 75 kg

Gross weight: 100 kg

Packaging: 900 mm x 650 mm x 750 mm

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

Print-out while start up - logging sequence 2 minutes

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PTA DISSOLUTION TEST INSTRUMENT TYP PTWS300 S/N: 10710
Product: Muster Batch: 007
Start Test: 04-19-2002 15:48 Test End: 04-19-2002 15:54
Nom. Speed: 50 rpm Nom. Bath Temperatur: 37.0 °C
pH Meter: not activated Test-Start Condition: all correct
Operator: PT
Info: Test

Wait for Corr. Par.: 04-19-2002 15:48
1. Start 04-19-2002 15:48
rpm: 50 Temp: 37.0 °C

2. Interval 1: 2min 04-19-2002 15:49
rpm: 50 Temp: 36.9 °C
T1: 36.5 T5: 36.2
T2: 36.2 T6: 36.4
T3: 36.4 T7: 37.0
T4: 37.0 T8: 36.3

3. Interval 2: 2min 04-19-2002 15:51
rpm: 50 Temp: 37.0 °C
T1: 36.8 T5: 36.2
T2: 36.2 T6: 36.7
T3: 36.7 T7: 37.2
T4: 37.2 T8: 36.5

End Runtime-Report ERRORS: 2
    
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Printed and filled OQ Forms

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PTA DISSOLUTION TEST INSTR. TYP PTWS300 S/N: 10710
 INSTALLATION at: 16.04.2002 OQ at: 19.04.2002
 LAST INSTRUMENT QUALIFICATION at: 19.04.2002

Set-Speed 050 rpm TOL. ± 4 % Meas.: 16 rpm (OK) (NOK)
 Set Bath Temp. 37.0 °C TOL. ± 0.5 °C Meas.: 37.1 °C (OK) (NOK)
 Set Vessel Tem. 37.0 °C TOL. ± 0.5 °C Meas.: 36.8 °C (OK) (NOK)
 Set pH1 Read. 6.80 pH TOL. ± 0.05 pH Meas.: 6.81 pH (OK) (NOK)
 Set pH2 Read. 7.00 pH TOL. ± 0.05 pH Meas.: 7.02 pH (OK) (NOK)
 Set pH3 Read. 7.00 pH TOL. ± 0.05 pH Meas.: 7.00 pH (OK) (NOK)
 Pump Volume 1.5 L/min TOL. ± 0.5 L Meas.: 1.51 L/min (OK) (NOK)

Wobble PADDLE (P) TOL. ± 0.50 mm
 Meas. Wobble P1 - P8 P1 - 0.01 P2 - 0.01 P3 - 0.00 P4 - 0.02
 P5 - 0.02 P6 - 0.01 P7 - 0.01 P8 - 0.01 (OK) (NOK)

Wobble Baskets (B) TOL. ± 0.50 mm
 Meas. Wobble B1 - B8 B1 - 0.01 B2 - 0.01 B3 - 0.01 B4 - 0.01
 B5 - 0.01 B6 - 0.03 B7 - 0.02 B8 - 0.01 (OK) (NOK)

Centricity PADDLE (P) TOL. ± 1.00 mm
 Meas. Centr. P1 - P8 P1 - 0.1 P2 - 0.1 P3 - 0.1 P4 - 0.1
 P5 - 0.1 P6 - 0.1 P7 - 0.1 P8 - 0.1 (OK) (NOK)

Centricity Baskets (B) TOL. ± 1.00 mm
 Meas. Centr. B1 - B8 B1 - 0.1 B2 - 0.1 B3 - 0.1 B4 - 0.1
 B5 - 0.1 B6 - 0.1 B7 - 0.1 B8 - 0.1 (OK) (NOK)

LEVEL PADDLE (P) TOL. ± 1 °
 Meas. Level P1 - P8 P1 - 0° P2 - 0° P3 - 0° P4 - 0°
 P5 - 0° P6 - 0° P7 - 0° P8 - 0° (OK) (NOK)

LEVEL Baskets (B) TOL. ± 1 °
 Meas. Level B1 - B8 B1 - 0° B2 - 0° B3 - 0° B4 - 0°
 B5 - 0° B6 - 0° B7 - 0° B8 - 0° (OK) (NOK)

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Depth Setting PADDLE (P) TOL. ± 2.00 mm
 Meas. Depth P1 - P8 P1 - 2.00 P2 - 2.01 P3 - 2.00 P4 - 2.01
 P5 - 2.01 P6 - 2.00 P7 - 2.01 P8 - 2.00 (OK) (NOK)

Depth Setting Baskets (B) TOL. ± 2.00 mm
 Meas. Depth B1 - B8 B1 - 2.00 B2 - 2.01 B3 - 2.01 B4 - 2.02
 B5 - 2.00 B6 - 2.00 B7 - 2.00 B8 - 2.00 (OK) (NOK)

* TOL. = tolerance MBAS. = measured OK = pass NOK = fail

List of Instruments and Reference Materials used to perform Qualification:

Speed Control Handy digit tachometer calibrated at 02.01.2002
 Temperature Testo 112 digit thermometer calibrated at 15.01.2002
 Wobbling SWT calibrated at 02.01.2001
 Centricity + Level digit caliper calibrated at 11.12.2001
 Depth Control " calibrated at "
 pH1 6.80 buffer Batch No. 02/11/02
 pH2 7.00 " Batch No. 01/37825
 pH3 7.00 " Batch No. 01/11753

Instrument OQ done by: _____ date: 16.04.02
 Dissolution Test Instrument Ready For Use (YES) (NO) Signature: [Signature]

Automation incorporating the PTWS 310

On-line Systems

This popular configuration is elaborate, but allows real time calculation of results using the **WINDISS 32 /Dissolution** Software and is by definition PC controlled.

With the TIDAS SA500 diode array photometer, a multi-cell-changer 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 (wizzard 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.

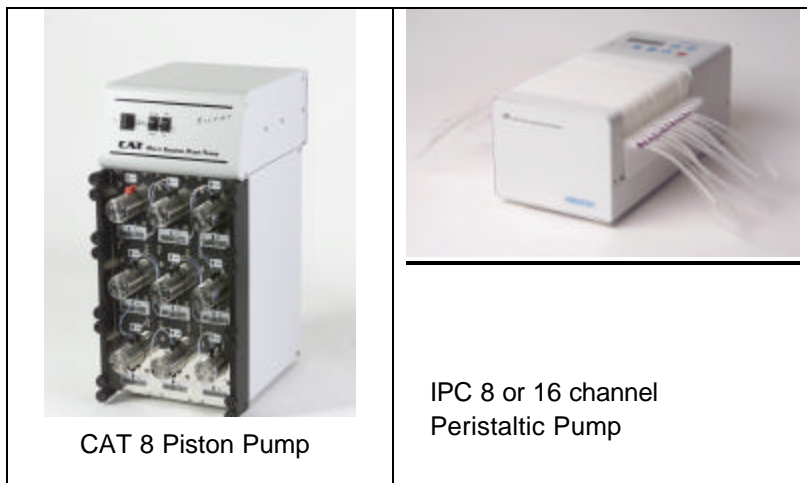
There are many spectrophotometer and auto sampler drivers available for connection to Pharma Test dissolution systems, even on-line HPLC, ask us..

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



Suitable Spectrophotometer with cell changers

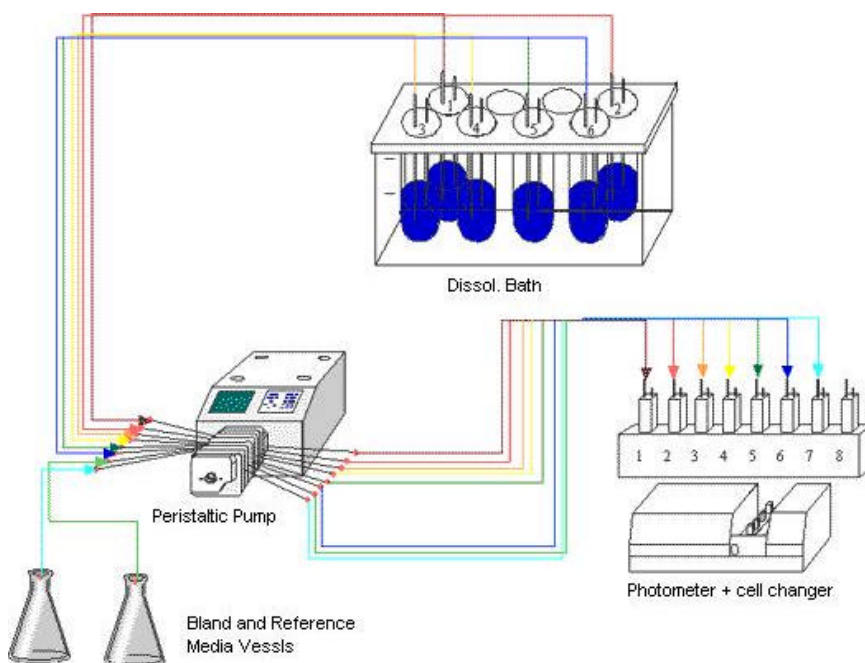
UV/VIS Diode Array Types:

TIDAS SA500 with 16-cell-changer, fibre optic system
 Agilent 8453 with 6- or 8-cell-changer

other UV/VIS Spectrophotometer Types:

Cecil CE 3200 with 8-cell-changer, Perkin Elmer Lambda, Shimadzu, Carry 50 etc..

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.