
**PTWS 4000**: 6 of 4 litre vessels in-line + 2 additional 1 litre USP vessels - easy manual sampling due to staggered start option - easy for automation - ideal instrument whenever concentration and sink conditions of the drug require more volume.

The PTWS 4000, is offering a all-in-one design of the six 4 litre vessels which affords easy and safe handling for correct tool height and sampling positions, unique instrument design and handling security. The ideal instrument for all USP <711/724> and EP <2.9.3/4> applications for which manual and/or automated operation is required due to its staggered stirrer start option.

Tablet dissolution testing is one of the most important tests during development and manufacturing of solid dosage forms, transdermals, ointments and creams, suppositories etc. 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 4000 offers both.

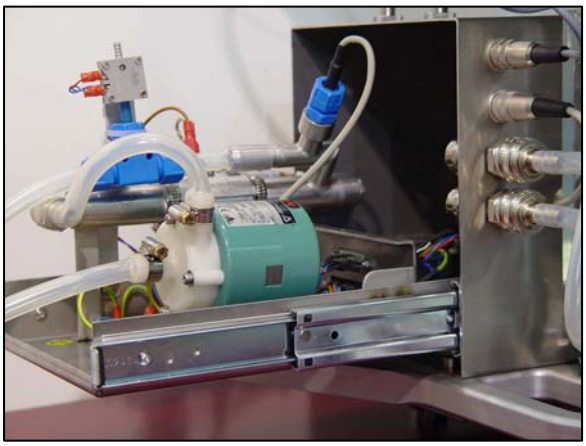
All test vessels are placed in one line of 6 vessels and 2 more 1 litre vessels in the second row. It is easy to remove spent samples and refill with solvent. The clear-view U-shaped Plexiglas water bath and the drainage tap make sure that the bath can be cleaned any time

**PHARMA TEST AG**
Siemensstrasse 5
D-63512 Hainburg (GER)

☎ +49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com

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 a separate stainless steel platform. This avoids vibration transfer from inside of the instrument. Test using USP Prednisone RS Tablets have clearly shown that vibration which exceed 0.00254 mm displacement has a tremendous influence to the release rate.

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.
This illustration shows the shafts equipped with stainless steel paddle blades. A total of 8 immersion positions operate within the PTWS 4000 system. They are mainly for the “Paddle-over-Disk” methods and adjust the drive head automatically. The access to the pump and heating system as well as the power connection is from the back side of the instrument.



Within the housing unit, the built-in circulation pump is spring loaded for totally vibration-free operation. 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 PHARMA TEST PTWS 610 tablet dissolution tester exceeds all technical requirements which are required by USP <711/724>, FDA, <2.9.3/4> European-, Japanese- and German Pharmacopoeias.

**Testing Method Filing:** additionally, the instrument can file testing methods which include information about stirring speed, sampling timing, duration time of EPE sampling probe inside the media etc. The number of testing methods filed on an USP memory stick is nearly unlimited. The user access administration of the filing system protects

the system from unauthorised actions. Using the built-in printer a print out of a short OQ as well as an instrument log report and settings is possible at the end of a run. This is a useful way to print and store hard copy run time logs of dissolution runs in compliance with current GMP practise.


The PTWS 4000 can also be used with USP/EP 1 litre Dissolution Vessels. A reduction ring is placed into the openings of the water bath cover, this will hold the 1 ltr. vessel version.

Additionally, the instrument can print out a short OQ as well as the instrument log and settings on an external data logger. This is a useful way to print and store hard copy run time logs of dissolution runs in compliance with current GMP practise.

***The PTWS 4000 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.
- User Access Control and Access Level Administration
- Free standing water bath for low vibration transmission
- No position change of drive head when changing stirring tools due to new mono-shaft design
- Staggered stirrer start option, necessary for manual operation as stirrers should start not before the sample is at the bottom of the vessel. Push down the stirrer shaft and rotation starts
- U-shaped water bath design for long life security including central drainage tap
- Clear LCD screen to display actual operational status; traffic light information to highlight any errors. Menu driven stirrer speed entry for the stirrer drive, display of actual speed of the stirrer drive motor
- 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 dual pillar drive system for the upper instrument head.
- Easy access to all 8 test vessels.
- Low evaporation vessel cover as standard supply.
- Additional 1 litre USP/EP 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 an external RS232 printer (PT-DL1).
- Calibration menu for stirrer speed, bath temperature, pH-probe.

**PHARMA TEST AG**
Siemensstrasse 5
D-63512 Hainburg (GER)

☎ +49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com

- RS-232 interface for full externally controlled operation and instrument data transfer.
- 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
- OQ/PQ auto information, performance sequence programmable.
- Instrument housing made out of stainless steel, always clean, GLP conforming.

**Options:**

- Optional pH-probe to read pH value of each vessel prior to and after a test run.
- UV protected glass vessels
- Various Tablet Sinkers
- pH-probe for online reporting the pH of the buffer or medium in one of the extra vessels
- Suppository Dialysis Cell **PTSW 0** for suppository dissolution testing
- Baskets in accordance to USP/EP apparatus 1, also gold plated with 10, 40 or 100 mesh sizes
- Felopine Basket option
- Paddle over disc options
- Trans-dermal patch tool option
- Ointment tool option (EP Extraction Cell)
- Sampling manifold (filtered), PT-MDS
- Calibration kit, includes optical tachometer, digital thermometer, wobble meter - all certified
- USP calibrator tablets and standards

***How does the PTWS 4000 operate ?***

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 water bath cover ensures correct positioning of the vessels with respect to the stirrer axis. All stirrers start either simultaneously or staggered when the PTWS 4000 is used for manual sampling. The big LCD screen will inform which fault has been detected, like low water level - temperature outside the tolerance - insufficient pump flow etc., while the information automatically is filed in the instrument's log.

**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 insitu sampling probes are placed into the vessels which stay inside during the entire test. 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.

**PHARMA TEST AG**
Siemensstrasse 5
D-63512 Hainburg (GER)

☎ +49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com

***Testing Method Storage Management***

The PTWS310/610/1210/4000 Series of Tablet Dissolution Testers offers a unique Testing Method Data Management System which uses an USB memory stick to file the programmed testing description (method). A method includes information of stirring speed, bath temperature, sampling sequences, sample probe immersion time, tool type, total testing time, user name, date, time, etc. All this information can be entered using the keyboard of the PTWS instrument or an external PC. The data are filed with an USB stick and so can be transferred to another PTWS Dissolution Bath easily.

This feature includes in addition access control for users. Different access rights can be allowed to a user group, such as Method Development, Instrument Qualification and Calibration, etc. A Quick-Start option allows to use the PTWS Dissolution Bath without to enter a valid Password.

**Technical Data PTWS 4000:**

| | |
|---|---|
| Display: | LCD Digital Display (10 x 10 cm illuminated) for RPM, temperature, time, timer and pH (optional) functions |
| Keyboard: | Function and alpha-numeric keys |
| Acoustic Signal: | Programmable acoustic signal for operator information |
| Interface: | 1 RS-232 port<br>1 TTL relay port to connect a PTFC 2 Fraction collector and a pump<br>1 pH-probe port |
| Printer: | Connect PT-DL1 data logger to print test log as well as OQ information |
| Speed control: | Adjustable from 20 rpm - 250 rpm |
| Accuracy: | ± 2% of set speed typically < 1% |
| Temperature control: | 2 off 750 W heaters and 1 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: | ± 0.3° C inside the water bath |
| Water circulation: | Water circulated through special diffusion system |
| 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 0.3 mm total run out |
| System tools: | Mono-shaft stirrer design, USP Apparatus 1, 2, 6 tool adapter, cream cell, trans-dermal patch tools - each tool individually coded |
| Vibration: | Pump system on vibration-free mounts, water bath on separate platform. |
| Vibration inside vessels: | Less than 0.003 mm displacement |

**PHARMA TEST AG**
Siemensstrasse 5
D-63512 Hainburg (GER)
☎ +49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com

| | |
|---|---|
| Vessel Centring: | Auto centring inside the bath cover, easily aligned bath using centring tools and stainless steel support dish |
| Test Vessels: | 4 litre USP vessels |
| Evaporation: | Low evaporation covers for all vessels, include suitable tool / sampling tube cut outs |
| 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 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 DSR X-Y-Z Sample Processor which can be connected directly to the PTWS 4000 or the ASP2000 Sample Handling System which requires the control by the WinDiss32 Software. Also the PTFC-2 fraction collector can be connected and controlled directly by the PTWS 4000 Dissolution Bath. For the media transfer either a peristaltic or piston pump are used.
- DRS and PTFC-2 are controlled by the PTWS 4000 built-in electronics - no software required !

Dimensions and Weights:

Net weight: 115 kg
Gross weight: 150 kg
Packaging: 1400 mm x 850 mm x 750 mm

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

***Automation incorporating the PTWS 4000…***

On-line Systems - closed loop

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 photometer, a 8-cell-changer for either 10x10 or 20x10mm path length cuvettes, 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.

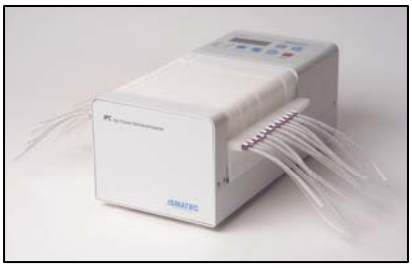
There are many spectrophotometer and auto sampler drivers available for connection to Pharma Test dissolution systems, even on-line HPLC, ask us..

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

Suitable Spectrophotometer with cell changers

UV/VIS Diode Array Types:

- SA500 with 8-cell-changer for 10x10 or 20x10mm path length cuvettes, fibre optic system
- Agilent 8453 with 6- or 8-cell-changer

other UV/VIS Spectrophotometer Types:

- PTA T70, Cecil CE 3200 with 8-cell-changer, Perkin Elmer Lambda, Shimadzu, Carry 50, Analytic Jena Specord, etc.

**PHARMA TEST AG**
Siemensstrasse 5
D-63512 Hainburg (GER)

☎ +49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com

***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.

**PHARMA TEST AG**
Siemensstrasse 5
D-63512 Hainburg (GER)

☎ +49 6182 9532-600
+49 6182 9532-650
email@pharma-test.de
www.pharma-test.com