

USP/EP Tablet Dissolution Test Instrument - Type PTWS 100S



The **PTWS 100S** is a 6 position, individual stirrer drive Compact Dissolution Tester for Solid Dosage Forms as described in chapter <711/724> USP and Section<2.9.3/4> EP as well as the DAB and Jap. Pharmacopeia <15>. It is supplied for individual speed control of each stirrer and a staggered start feature for each of the 6 positions. The upper drive is electronically controlled so as to offer two positions: an upper cleaning and a lower working position. The electrically driven lift mechanism is centrally located above the water bath thus assuring that the whole lift drive mechanism is positioned so that the tool shafts are always kept parallel and at 90° to the vessel walls when in the working position.

The dissolution vessels are automatically centred and held in position by the unique vessel covers once inserted into the instrument support frame work. The access points which are necessary for sampling as well as the openings for the tools are contained in an auxiliary, low evaporation loss, vessel cover.

The blow moulded water bath and its cover can easily be removed from its support frame for cleaning purposes. The bath cover can also be easily unscrewed for cleaning. The water bath contains a water diffuser for faster heating and so that heated water is evenly distributed throughout the bath.

The heating system is contained in a separate stainless steel housing. The connections between the heater and the bath are on „quick connect“ fittings for easy connection and disconnection. Water is pumped through the system using a powerful, yet quiet, circulation pump. The pump itself is spring mounted (to limit vibration transmission) and the flow through heater is protected from overloading (overheating in case of control electronic's failure) via a

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thermal fuse as well as a thermo switch for added security; with service and maintenance in mind, access to the compact pump and heater section is easily achieved without having to move the main frame instrument.

The tool design is Mono-shaft™ throughout. Tools are made up of the main drive shaft plus interchangeable tool heads (adapter). The main tool shaft remains in place regardless of the tool type. The clearance of each tool from the vessel base will automatically be correct once the main tool shaft has been installed and qualified with any one of the tool sets. Each stirrer can be raised by hand into a convenient position for easy vessel removal or insertion.

A key point in today's crowded labs is the footprint of the PTWS 100S. The space saving construction of the PTWS 100S is so designed as to be able to offer a 2 x 3 or a 3 x 2 configuration with a minimal space requirement of 56cm x 78cm (w x d).



In keeping with our cutting edge design, a „Touch Screen“ allows control of the various mechanical features of the instrument such as the tool speed, lift drive and heater. The instrument set up is menu driven. Visual signals on the display inform the user of the status of critical instrument parameters, e.g., bath target temperature not reached. Access to the instrument can be password controlled if required upon boot up. If certain operational parameters form a regular feature of the daily

routine, then these can be incorporated into a test Method for faster set up. These parameters can be tool speed, target bath temperature, sampling time points and so on. The test method memory capacity is almost limitless. For help with the most critical Menu points you can access an on line help assistant directly on the display. As soon as the test is started, a screen saver can be activated with the most important information displayed in large script.

Options:

- Interface for remote control applications and print-out via RS232, USB
- I/O Interface for direct control of peripheral instruments such as a PTFC-2 Fraction Collector.
- The 2 litre vessel version can also be used with 1 litre vessels.
- Individual spindle drive and electronically controlled staggered stirrer start
- Coloured vessels available for UV sensitive test materials.

Features of the standard instrument:

- **PTWS100S** is offering individual speed control for all 6 stirring stations or grouping into 3x2, 2x3 or 1x6 drives , uses electronically controlled stepper motors and individual toothed belt drive
- Staggered start for all tool positions.
- Mono-shaft™ tool design for each tool position.
- Blow moulded water bath design.
- Warm water diffuser element for even heat distribution throughout the bath.

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- Cover with automatic vessel centring feature.
- A centrally located electronically controlled lift drive to raise and lower the head.
- built-in timer to program sampling sequence information, including acoustic and optical information
- audible and visible information about sampling times
- run-time clock, count down mode
- user information screen showing for 5 seconds Stirrer Speed, Bath Temperature, Batch Number, Time to take Sample, Operating Time. Information scrolls continuously during operation
- wake up time to start heating - energy saving mode (requires that mains current is available)
- optical information from the instrument display informing the instrument status by different colours (green = ready to use - red = not ready yet - yellow = prepare to use)
- external heating device including overheating protection - no water - no heating, thermo switch and thermo fuse to protect heater, includes status LED to indicate "ready - heating - off"
- water diffuser tube inside the water bath for faster temperature distribution
- calibration and adjustment program for temperature control, speed control
- User password access if required (4-level).
- Testing method filing (up to about 200 different descriptions)
- PQ interval warning.
- Screen saver function with critical information display.

Automation:



PTFC2 Fraction Collector for automated Sampling with automated media refilling option.

For automated fraction collection the PTFC2 Collector as well as a Peristaltic or Piston Pump can be added to the PTWS 100. Sampling sequence timing, sampling volume and the optional media refilling process are programmed using the user menu of the PTWS 100 instrument. In-situ sampling ferrules are placed into the PTWS 100 through the top cover holes. Each ferrule holds a 5

or 10 μ PP Sinter Filter. When the tablets have been dropped into the dissolution vessels the automated sampling start. If the refilling option is used automatically media refilling will start after a sample has been withdrawn.

Use the PT-DL1 to print the Runtime Log of the PTWS 100

The PT-DL1 is connected to the RS232 interface of the PTWS 100 (option). It includes the printout of the following information's:



- Programmed logging sequence
- total number of logs
- selected printing language
- Instrument serial number
- Firmware Release number
- Operation Audit Trail, including Instrument status of heater (on/off), stirrer (on/off)
- Target bath temperature and stirrer speed setting
- actual bath temperature and stirrer speed at each logging sequence

PTWS 100S Technical Data (1 ltr. version):

Display:	LCD Display, illuminated
Data Entry:	Touch sensitive glass plate, functional touch keys
Acoustic Signal:	Programmable acoustic signal for operator information
Timer:	Programmable sampling times, wake-up and sleeping mode, operation time information and count-down mode
Printer:	External Data Logger
Speed Control:	individual or grouping control for all 6 stirrer within the range of 20 - 220 RPM
Accuracy:	± 2% of set speed, typically < 1%
Stirrer Shaft Wobble:	Better than 0.2 mm total run out
System Tools:	Mono-shaft stirrer design, USP/EP apparatus 1, 2,5,6 tool adapter, cream cell, trans-dermal patch tools, each tool and vessel individually coded
Heater Range:	25 - 45°C
Accuracy:	± 0.2°C inside the water bath
Water Circulation:	Water circulated from external heating system through special diffuser inside the water bath
Vibration:	External Heating System, inside
Number of stirred vessels:	6 (3 + 3)
Standard Vessels:	1 litre USP/EP Borosilicate glass vessel, each one individually coded
Heat-Up:	Energy saving, programmable, "auto-start" heater function and programmable sleeping mode"
Calibration:	Built-in calibration procedures for speed, temperature control, OQ/PQ sequence programmable including alarm indicator
Bench Space:	45 x 65 cm (2 by 3) or 65 x 45 cm (3 by 2)
Certification:	All components certified to USP / EP requirements
CE / EMC Certification:	All CE / EMC Certification provided
Validation:	All IQ & OQ paperwork included

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Automation:

- Using a 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 monochromatic spectrophotometers, preferable double beam and scanning versions, like the T70, Cecil CE, Perkin Elmer Lambda etc.

Sampling System:

- Sample fractions using the DSR X-Y-Z Sample Processor which can be connected directly to the PTWS100 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 100 Dissolution Bath. For the media transfer either a peristaltic or piston pump are used.
- DSR and PTFC-2 are controlled by the PTWS 100 built-in electronics - no software required !

Dimensions and Weights:

Net weight: 60 kg

Gross weight: 80 kg

Packaging: 700 mm x 650 mm x 650 mm

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