

PTWS 4000

USP/EP Tablet Dissolution Testing Instrument

The PTWS 120D is a 6 position, single drive compact tablet dissolution testing instrument for solid dosage forms as described in USP chapter <711/724> and EP section<2.9.3/4> as well as the BP, DAB and Japanese Pharmacopeia section <15>. Its design for manual operation and ease of use.



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.

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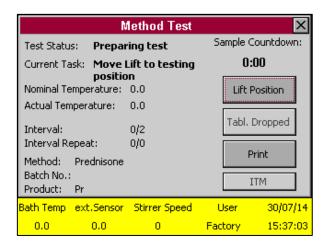
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User Interface

In keeping with our cutting edge design, a large color, touch screen allows control of the various mechanical features of the instrument such as the tool stirring speed, lift drive and heater. The instrument control is menu driven using a resistive touch screen and selection wheel technology. 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.



As soon as the test is started, a screen saver can be activated with the most important information displayed in large script, like count-down timer so that this information remains visible even at time when the operator is not standing directly in front of the instrument.

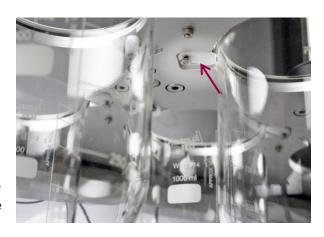
Stirring Tools



The PTWS 120D uses the Pharma Test
MonoShaft™ design. Tools consist of the main
shaft plus interchangeable tool heads (adapters).
The main shaft remains in place in the
instrument regardless of the tool head being
used. The clearance of each tool from the vessel
base will always be correct once the main tool
shaft has been installed and qualified with any
one of the tool sets once. Each stirrer can be
raised by hand into a convenient position for easy
vessel removal or insertion. PTWS 120D is
capable to perform a staggered start for each of
the six positions, which is essential in manual
operation.

Vessel Centering System

The PTWS 120D features a rigid and precise three-point individual centering system for each dissolution vessel (picture shows view from below). The vessels are held in position by three adjustable noses and are inserted into the instrument support framework. The access points for sampling as well as the openings for the tools are contained in an auxiliary, low evaporation, vessel cover. Each USP Borosilicate glass vessel has a batch code on top of the flange for easy visibility and positioned placement inside the water bath cover.



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Lift Mechanism



The upper drive is motorized and electronically controlled it offers eight programmable positions: an upper cleaning and instrument qualification position and lower working positions are programmable depending on the type of stirring tool used. The upper position offers ideal access to the stirring tools and vessels for a change of tools and cleaning steps between the dissolution tests. The motorized drive head lifting mechanism is positioned in a way so that the tool shafts are always kept parallel and at a 90° angle to the vessel walls when in the working position.

Space Requirements



A key point in today's crowded labs is the footprint of the PTWS 120D. The space saving design of the PTWS 120D offers the user the choice between a 2x3 or a 3x2 configuration with a minimal space requirement of just 45cm by 65cm (width by depth). The display module can be mounted either of two positions on the drive head of the PTWS 120D instrument.

Advantages

- » Single drive of 6 stirring positions
- » Modular design to minimize bench space requirements
- » 3-point individual vessel centering system
- » Borosilicate glass vessels including extra low evaporation vessel covers

Features

- » Fully USP <711/724> and EP <2.9.3/4> compliant
- » CAN Bus technology offering instrument suitability check prior to start of a test run
- » Staggered start capability
 - Vessel low evaporation sealing covers
 - Removable water bath for easy cleaning
 - > Drainage tap to empty the bath
 - > Method management and CFR compliant user administration
 - > User Access control
 - > Optical and acoustic signals to inform about sampling intervals,
 - > Timer count down function
- » Traffic Light optical information on display shows the instrument status by different colors (green = ready to use, yellow = preparing to use, red = error encountered)
- » OQ, PQ interval warning with programmable interval
- » USB port for remote control of the PTWS 120D

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Standard Scope of Supply

The PTWS 120D comes ready to use with the following standard scope of supply:

- » One set of stainless steel paddles
- » One set of batch coded 1000ml Borosilicate glass vessels
- » One set of depth adjustment balls
- » One bottle of ALGEX water preservative
- » Comprehensive documentation folder including:
 - > User manual
 - > DQ/QC instrument compliance test certificate
 - > IQ documentation
 - > 0Q documentation
 - > Instrument logbook
 - Compliance certificates for vessels and stirring tools

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

- » PTWS 120S instrument variant with individual stirrer speed settings for each station
- » Direct control of peripheral instruments via I/O port such as PTFC-2/8 fraction collector or DSR-M Dissolution Sampling Robot
- » Eco saving double walled vacuum molded water bath
- » 2 liter vessel version (can also be used with 1 liter vessels)
- » 250 ml Mini Vessel set incl. mini paddle stirrers
- » Amber colored vessels for UV sensitive test materials
- » Full range of MonoShaft™ stirring tools available
- » Full range of certified validation tools available
- » PT-RP80 serial report printer

PT-RP80 Report Printer

Use the PT-RP80 serial report printer to print out the runtime report of the PTWS 120D.



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Example Runtime Report

RUN TIME REPORT

PHARMA TEST PTWS120D

S/N: 19018 V: 1.00

PRINT DATE/TIME: 02.02.2015 12:31:48 USER NAME: ADMIN PRODUCT NAME: PRODUCT1 METHOD NAME: METHOD1

BATCH: 1

BATH TEMP NOM.: 37.0 BATH TEMP ACT.: 36.9 LIFT: USP 1

VOLUME: 900ml DURATION: 0:10 SPEED: 50

I.-COUNT1: 1
I.-DELAY1: 0:01
I.-COUNT2: 1
I.-DELAY2: 0:02
I.-COUNT3: 0
I.-DELAY3: 0:00

TEST STATUS: NO ERRORS

START: 02.02.2015 12:21:08 END: 02.02.2015 12:31:08

INT.1:

02.02.2015 12:22:08 BATH TEMP ACT.: 36.8

INT 2.

02.02.2015 12:24:08 BATH TEMP ACT.: 36.9

OPERATOR

NAME

SIGNATURE

Type of the instrument (PTWS 120D) Serial number of the instrument

Firmware version installed on the instrument

Date and time of this print out Name of the user currently logged in Name of the product used for this test Name of the method used for this test

Batch number entered at the start of this test Nominal bath temperature from the method for this test Actual bath temperature at time of the print out Name of the lift position from the method for this test Media volume from the method for this test

Total duration time setting for the method for this test Nominal speed setting from the method for this test

First interval count First interval delay Second interval count Second interval delay Third interval count Third interval delay

Current status of the test, if test is still running it will be

"IN PROGRESS"

Start date and time of the test

End date and time of the test (if already finished)

Occurrence of first interval Date and time of first interval

Actual bath temperature when first interval occurred

Occurrence of second interval Date and time of second interval

Actual bath temperature when first interval occurred

If no intervals have yet occurred it will be "NO INT"

Space to write down name of the operator

Space for the operator's signature

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Technical Data

Parameter	Specification
Display	LED Display showing number of tests and hardness result
Data Entry	Numerical and Functional keys
Standard Force Range	5.0 to approximately 300N
Accuracy	< 1N
Resolution	0.074N (300N model) - 0.1482N (500N model) - 0.2964N (1000N model
Force Settings	Linear speed or linear force increase
Selectable Range	5.0 - 200 N/Second or Millimeter/Minute
Accuracy	< 2% force or < 0.1% speed
Maximum Sample Size	45 mm
Drive Way Setting	1.0 - 30.0 mm to adapt sample size
Printer	Internal thermal printer
Interface	Serial RS232 COM port
Calibration Guidance	Built-in calibration procedures the digital load cell
Adjustments	Two point adjustment - zero and 10kg
Calibrations	Multiple point for load cell precision using certified weights (CAL15)
Force Detection Reproducibility	PT-MT Magnetic Tablet
Instrument Housing	Stainless Steel to meet GLP requirements
Bench Space Requirement	L 48cm x W 24cm x H 26cm (without external printer)
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

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

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