PTWS 120D

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>. It is designed for manual operation and ease of use.

PTWS 120D 6-position Dissolution Tester

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

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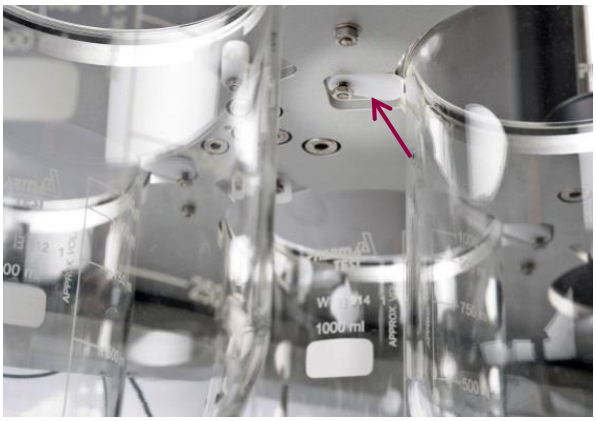
Stirring Tools

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.

Vessel Centering System

The PTWS 120S 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.



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.

Heating System

The heating system is contained in a separate stainless steel housing. The connections between the heater and the bath are made by "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 electronics failure) via a 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 body of the instrument.

Vacuum-Moulded Water Bath

The vacuum molded water bath can easily be removed from the 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 to ensure that heated water is evenly distributed throughout the whole bath. A double walled vacuum molded water bath is the standard configuration to reduce the heat transfer to the outer environment saving internal heating and external cooling.

Space Requirements

A key point in today's crowded labs is the footprint of the PTWS 120S. The space saving design of the PTWS 120S 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 120S 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
- Individual vessel batch code at the top of the vessel flange for easy identification
- Excellent access to all vessels
- Eco saving double walled vacuum molded water bath
- Motorized Drive Head lifting mechanism including head position programming facility
- Screen saver functionality and count-down timer offers most important information at a glance (stirrer speed, bath temperature, time to next sampling interval, elapsed time, media temperature etc.)
- Wake up functionality to start heating at a pre-programmed time
- Ultra-fast heating system due to newly designed heat exchanger, saves up to 1/3rd of the heating up time compared to most other models
- MonoShaft™ system to avoid re-adjustment of immersion depth
- Staggered stirrer start feature for convenient manual sampling
- Water diffuser inside the vacuum moulded water bath for even temperature distribution and fast temperature equilibration
- Spring loaded pump assembly to eliminate vibration transfer
- Extraordinary safety features for pump and heating system, flow control, digital temperature control, thermo switch, thermo fuse
- Auto stirrer stop when drive lift is moved
- Excellent stirrer shaft verticality inside the vessels due to central position of lift columns, drive head assembly and rigid anodized aluminum framework
- Easy removal of the water bath from of the frame work for cleaning and maintenance work
- Energy saving double walled bath option, less heat transfer into the lab environment, less power consumption during instrument operation
- DQ/QC, IQ and OQ documents included free of charge

Features

» Fully USP <711/724> and EP <2.9.3/4> compliant
» 6 single drive motorized stirred positions
» Centrally located motorized lift drive to raise and
» lower the drive head
» Individually coded Borosilicate vessels
» File up a nearly unlimited number of different test descriptions (methods)
» 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
» RS-232 port to connect a serial PT-RP80 report printer, printing date/time, sampling time information, selected sampling position, used stirring tools, media temperature, operator name etc.
» I/O port for remote control of external instruments in automated applications, like DSR-M, Pumps and PTFC-2/8

Standard Scope of Supply

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

» Eco saving double walled vacuum molded water bath
» 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
  › OQ 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:

» Direct control of peripheral instruments via I/O port such as PTFC-2/8 fraction collector or DSR-M Sampling Robot
» 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 120S.

Example Runtime Report

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RUN TIME REPORT
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PHARMA TEST PTWS120S
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 Pos.1: 50
SPEED Pos.2: 50
SPEED Pos.3: 50
SPEED Pos.4: 100
SPEED Pos.5: 100
SPEED Pos.6: 100

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
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.............................
OPERATOR
NAME
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.............................
SIGNATURE
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Type of the instrument (PTWS 120S)
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 settings from the method for this test
(different speed settings for each station are possible)

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

Technical Specifications

Parameter	Specification
Display	6", 320x240 pixel color LCD, illuminated
Data Entry	Resistive touch screen, functional touch keys
Acoustic Signal	Programmable acoustic signal for operator information
Timer	Programmable sampling times, wake-up and sleeping mode, operation time information and timer count-down mode
Stirrer Position	8 programmable stirrer immersion positions (paddle over disk, transdermal cylinder etc.)
Testing Method Programming	Unlimited number of different test descriptions can be stored on SD card
User Access Control	Multiple level access control, CFR compliant
OQ, PQ control	Programmable time periods to remind on QO or PQ testing
Printer	External PT-RP80 report printer using long-life printer paper
Number of Stirred Vessels	6 (3 by 2 or 2 by 3 arrangement)
Standard Vessels	1 liter USP/EP Borosilicate glass vessel, each individually coded
Vessel Covers	Ultra-low evaporation design (< 0.7% within 24h)
Stirring Speed Control	25 - 250 RPM
Speed Accuracy	±2% of set speed, typically < 1%
Stirrer Shaft Wobble	Better than 0.2 mm total run out
System Tools	MonoShaft™ stirrer design, USP/EP apparatus 1, 2, 5, 6 tool adapter, cream cell, transdermal patch tools, each tool and vessel individually coded
Heating System	Pump for water circulation and 1500W heater for fast heating up (230/240V units only)
Heater Range	25 - 45°C
Heater Accuracy	± 0.2°C inside the water bath
Heat Up Process	Energy saving, programmable "wake up" heater function and "sleep mode"
Water Circulation	Water circulated from external heating system through special diffuser inside the water bath
Vibration Elimination	External heating system, spring loaded pump assembly
Calibration	Built-in calibration procedures for speed, temperature control, OQ/PQ interval programmable including alarm indicator
Bench Space Requirement	45 x 65 cm (2 by 4) or 65 x 45 cm (4 by 2)
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.