PTWS 1220

USP/EP Tablet Dissolution Testing Instrument

The PTWS 1220 is a 6 + 6 position, single drive 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 DAB/BP and Japanese Pharmacopeia section <15>. The instrument features two additional vessels (approx. 250ml) for media refilling and reference standard media. The PTWS 1220 is the ideal choice for Biowaiver studies and dissolution method development.

PTWS 1220 USP/EP Tablet Dissolution Testing Instrument

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. Status messages and color changes on the display inform the user of the status of critical instrument parameters, e.g. bath target temperature not reached. A status bar provides a quick overview and uses the familiar traffic light system green – yellow – red.

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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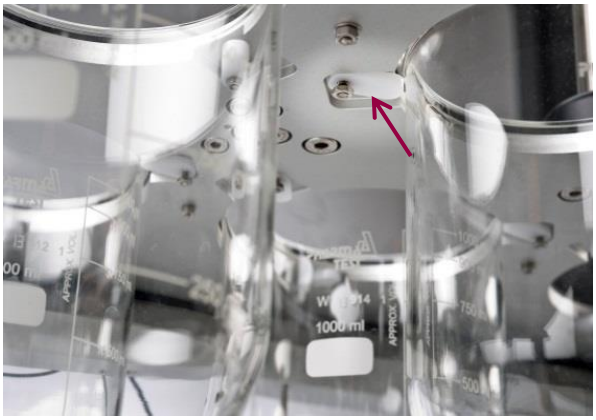
Stirring Tools

The PTWS 1220 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 fixed in its position.
A wide variety of different stirring tools is available while the standard configuration includes USP/EP App. 2 Paddle stirrers.

Vessel Centering System

The PTWS 1220 features a 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. Each vessel is correctly centered against the stirring tool, while this position is secured even when the vessels are removed for cleaning and placed back afterwards. The access points for sampling as well as the openings for the tools are contained in an auxiliary, low evaporation, vessel cover.



Lift Mechanism

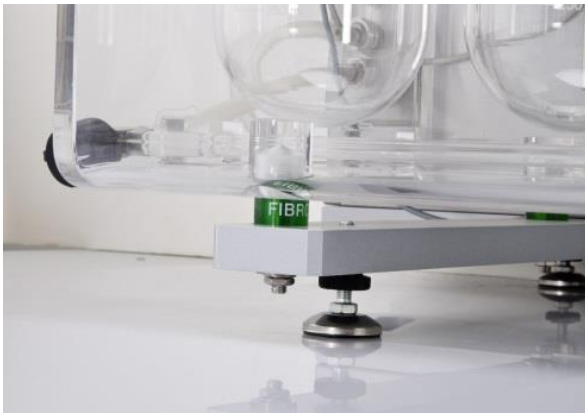
The upper drive is motorized and electronically controlled it offers eight programmable positions: an upper cleaning position and lower working positions are programmable depending on the type of stirring tool used. The upper position offers ideal access to the stirring tools and vessels for a change of tools and cleaning steps between the dissolution tests. The rigid design of the electronically driven lift mechanism ensures that the whole lift drive 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 ultra-fast heating system is installed on an easy to remove platform within the stainless steel housing. The heat up time of the water bath has been reduced by approx. 40% compared to previous models. Access to pump, heater and all safety sensor system is possible without to move the bath from its qualified position. 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.

Water Bath

The U-shaped water bath rests on vibration absorbers to avoid any vibration transfer from either inside the instrument or even from external equipment placed on the same bench surface, to satisfy the requirements from USP <711>. 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 tap allows emptying the bath if this is required.



Automation Capabilities

The motorized EPE-1220 sampling system lowers the sampling probes into the media and after sampling raises them back out again. 8 different sampling positions can be programmed. The ITM-1220 individual media temperature monitoring system is attached to the EPE-1220 and will read and report the vessel media temperatures while sampling. The manual TM-1220 or motorized TMA-1220 tablet dropping magazine completes the set of useful accessories for automation. It covers all vessels and ensures low evaporation rates during the dissolution test. The magazines include magnetic holders for the tube cleaning device.

Offline Sampling and Sample Preparation

For offline automation with fraction collection the PTFC-16 fraction collector as well as either PT-SP multiple syringe pumps, an IPC peristaltic pump, or a CAT piston pump can be added to the PTWS 1220. Using the PTWS 1220 within an automated system offers the operator full access to the vessels before and at the end of a run as the complete drive head is lifted electronically. Sampling sequence timing is programmed using the menu system of the PTWS 1220 instrument, while sampling volume and the optional media refilling process is programmed at either the PTFC-16 or DSR-M.

No external software is necessary in this system. The motorized sampling system EPE-1220 is used to lower the sampling probes while sampling into the dissolution vessels. When sampling is finished the sampling probes are raised out of the media and the system waits for the next cycle. Each sampling probe holds a PP sinter filter (usually 5 or 10µ). When the tablets have been dropped into the dissolution vessels the automated sampling process starts. If the refilling option is used media refilling will start automatically after a sample has been withdrawn.

Connection to Dissolution Sampling Robot

It is also possible to use the DSR-M dissolution sampling robot which features the capability of sample dilution and media refilling. The DSR-M offers excellent sampling and refilling accuracy via the fully integrated valve-less piston pump module. Sampling time and interval control is programed the PTWS 1220 while volume, dilution ratio and refilling option are set at the DSR-M instrument.

Closed Loop Online Systems

For an online automated system it is possible to use a UV/VIS spectrophotometer with a multiple-cell-changer. The spectrophotometer and pump of such a system is controlled by the powerful WinDiss ARGUS dissolution software. WinDiss ARGUS features drivers for most commonly available UV/VIS spectrometer types, like Agilent 8453 Diode Array, or conventional UV/VIS monochromatic spectrophotometers (preferably double beam and scanning versions) such as the T70, Analytic Jena Specord SP 200, Cecil CE and Perkin Elmer Lambda series as well as drivers for many popular types of pumps.

Advantages

» Individual speed control for front and back row of stirrers
» 6 front line and 6 back line vessels for easy access in manual operation
» Rigid aluminum water bath cover
» Individual 3-point vessel centering
» Excellent access to all vessels
» Staggered start feature for convenient manual sampling
» Screen saver functionality 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
» Programmable infinity test
» MonoShaft™ system to avoid re-adjustment of immersion depth
» Ultra-fast heating system with excellent temperature stability due to newly designed heat exchanger
» Water diffuser for even temperature distribution
» Vibration absorber to avoid vibration transfer into the USP/EP vessels
» Spring loaded pump assembly to eliminate vibration transfer to the frame work
» Extraordinary safety features for pump and heating system, flow control, digital temperature control, water level sensor, thermo switch, thermo fuse
» DQ/QC, IQ and OQ documents included free of charge

Features

» Fully USP <711/724> and EP <2.9.3/4> compliant
» 12 stirred positions in a 6 + 6 arrangement, 2 extra vessels for refilling or standard media
» Rigid motorized lift drive to raise and lower the head
» Individually coded Borosilicate vessels
» File up a nearly unlimited number of different test descriptions (methods)
» Instrument suitability check prior to start of a test run
» Staggered start capability
» Vessel low evaporation sealing covers
» Drainage tap to empty the bath
» CFR compliant method management and user administration with access control
» Built-in thermo printer to print a test-log at the end of a run
» Optical and acoustic signals to inform about sampling intervals, timer count down function
» Status bar with traffic light 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
» Interfaces: USB port for remote control of the PTWS 1220, RS-232 port to connect serial devices, I/O port for remote control of external instruments in automated applications, like DSR-M, pumps and PTFC-16
» Calibration menu for stirrer speed, bath temperature

Standard Scope of Supply

The PTWS 1220 comes ready to use with the following standard scope of supply:

- One set of stainless steel paddles
- One set of 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-16 fraction collector or DSR-M Sampling Robot
- Amber colored vessels for UV sensitive test materials
- Full range of MonoShaft™ stirring tools available
- Full range of certified validation tools available
- EPE-1220 motorized sampling system
- ITM-1220 media temperature monitoring system
- TM-1220 manual tablet drop magazine
- TMA-1220 automated tablet drop magazine
- Cleaning system for sampling probes and tubing featuring magnetic holders

Example Runtime Report

PTWS 1220 features a built-in thermo printer for result reporting:

```
RUN TIME REPORT

PTWS D1220
SN: 20680
V: 1.00
Print Date / Time
15/09/15 15:13:02
USER NAME: Pharma Test
METHOD NAME: ptag
BATCH: 1a
BATH TEMP NOM.: 37.0
BATH TEMP ACT.: 36.9
LIFT POS: USP 1+2
DURATION: 0:10
SPEED NOM1: 50
SPEED 1: 50
SPEED NOM2: 100
SPEED 2: 100
I.-REPEAT1: 1
I.-DELAY1: 0:1
I.-REPEAT2: 1
I.-DELAY2: 0:2
TEST STATUS: NO ERRORS
START: 15/09/15 15:05
END: 15/09/15 15:08:32

INT 1: 1/1
15/09/15 15:06:32
BATH TEMP ACT: 37.0
SPEED ACT1: 50
SPEED ACT2: 100

INT 2: 1/1
15/09/15 15:08:32
BATH TEMP ACT: 37.1
SPEED ACT1: 50
SPEED ACT1: 100
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.....
OPERATOR NAME
```

```
.....
SIGNATURE
```

Type of the instrument (PTWS 1220)
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
Total duration time setting for the method for this test
Nominal speed setting for each row from the method for this test
First interval number of iterations
First interval delay
Second interval number of iterations
Second 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 and stirring speeds when first interval occurred

Occurrence of second interval
Date and time of second interval
Actual bath temperature and stirring speeds when second 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"- 320*240 pixel color LCD, illuminated
Data Entry	Resistive touch screen, alpha-numerical and functional keys
Acoustic Signal	Acoustic signal for operator information at programmable intervals
Timer	Programmable sampling times, wake-up and sleeping mode, operation time information and timer count-down mode
Stirrer Position	8 freely programmable stirrer immersion positions (paddle over disk, transdermal cylinder etc.)
Testing Method Descriptions	Unlimited number of test descriptions can be stored on SD card
User Access Control	Multiple level access control
OQ, PQ control	Programmable time periods to remind about QO or PQ testing
Printer	Built-in thermo printer
Number of Stirred Vessels	12 (6 + 6 arrangement)
Standard Vessels	1 liter USP/EP Borosilicate glass vessel, each individually coded
Stirrer Speed Settings	Independent setting for front and back row of stirrers
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, tools & vessels individually coded
Heating System	Pump for water circulation and 1400W heater for fast heating up
Heater Range	25 - 45°C
Heater Accuracy	± 0.2°C inside the water bath
Heat Up Process	Energy saving, programmable "wake up" function and "sleep mode"
Water Circulation	Water circulated from external heating system through special diffuser inside the water bath
Vibration Elimination	Water bath rests on vibration absorbers, spring loaded pump assembly
Calibration	Built-in calibration procedures for speed, temperature control, OQ/PQ interval programmable including alarm indicator
Bench Space Requirements	Approx. 112 x 58 cm
Packaging	Approx. 137 x 78 x 87 cm (W x D x H)
Weight	75 kg net weight, 100 kg gross weight
Certification	All components certified to USP / EP requirements

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