

PTWS 1210 – USP/EP Tablet Dissolution Testing Instrument



The PTWS 1210 is a 6 + 6 stirred 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>, having 2 extra beakers to take media refilling and reference standard media. The PTWS1210 is the ideal choice for Bio-Waiver studies and Dissolution Method Development.

User Interface



In keeping with our cutting edge design, a large LC Display informs of the various mechanical features of the instrument such as the tool stirring speed, lift drive and heater. The instrument control is menu driven. Visual signals on the display inform the user of the status of critical instrument parameters, e.g. bath target temperature, stirring speed etc. 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, the display shows the most important information so that this information remains visible even at time when the operator is not standing directly in front of the instrument. The user access administration of the filing system protects the system from unauthorized actions. The traffic light information center 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.

Stirring Tools



The PTWS 1210 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 1210 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.

evaporation, vessel cover.

The access points for sampling as well as the openings for the tools are contained in an auxiliary, low

Lift Mechanism

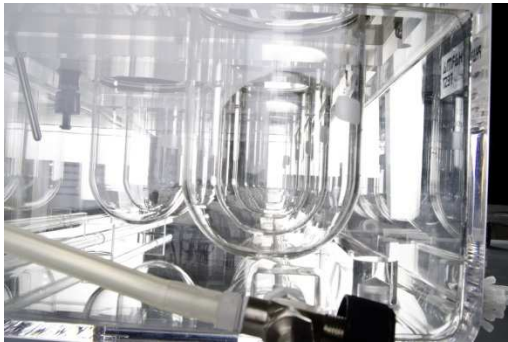
The upper drive is motorized and electronically controlled it offers eight programmable positions: an upper cleaning position and lower working positions are programmable depending on the type of stirring tool used. The upper position offers ideal access to the stirring tools and vessels for a change 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 contained in a easy to remove platform within the stainless steel housing. 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. 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 should be required.

Automation Capabilities



Motorized Sampling System EPE-1210 which lowers and rises the sampling ferrules into the media and after sampling back out again. 10 different sampling positions can be programmed. ITM-1210 Media Temperature Monitoring system which is attached to the EPE-1210 will read and report the media temperature while sampling. And a manual or motorized Tablet Dropping Magazine TM/TMA-1210 with its attached low evaporation vessel sealing covers complete the set of useful accessories for automation.

Offline Sampling and Sample Preparation



For offline automation with fraction collection the PTFC 16 fraction collector as well as either a IPC 12 channel peristaltic pump, two PT-SP8 multiple syringe pumps or a CAT piston pump can be added to the PTWS 1210. Using the PTWS 1210 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 1210 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-1210 is used to lower the sampling ferrules while sampling into the dissolution vessels. When sampling is finished the sampling ferrules are raised out of the media and the system waits for the next cycle. Each sampling ferrule holds a 5 or 10 μ PP sinter filter. 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.



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 programmed the PTWS 1210 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 Analytic Jena Specord SP200 or the Perkin Elmer Lamda series as well as drivers for many popular types of pumps.

Advantages



Some of the highlights the PTWS 1210 offers are:

- 6 front line and 6 back line vessels for easy access in manual operation
- Individual 3-point vessel centering
- Excellent access to all vessels
- Screen information offers most important information at a glance (stirrer speed, bath temperature, time to next sampling interval, elapsed time)
- Wake up functionality to start heating at a pre-programmed time
- Ultra-fast heating system with excellent temperature stability
- 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
- MonoShaft™ system to avoid re-adjustment of immersion depth
- Staggered start feature for convenient manual sampling
- DQ/QC, IQ and OQ documents included free of charge

Features

The main features of the PTWS 1210 are:

- Fully USP <711/724> and EP <2.9.3/4> compliant
- 12 stirred positions
- Rigid motorized lift drive to raise and lower the head
- 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
- Method management and user administration
- User access control, password expiry 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
- 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
- Interfaces – USB port for to use the memory stick, RS232 port for external control; I/O port for remote control of external instruments in automated applications
- Heater safety system includes thermo-switch, thermo-fuse and flow-sensor
- Calibration menu for stirrer speed, bath temperature, pH-probe
- Heater wake-up and sleeping mode for less energy consumption

Standard Scope of Supply

The PTWS 1210 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-1210 motorized sampling system
- ITM-1210 media temperature monitoring system
- TM-1210 manual tablet drop magazine
- TMA-1210 automated tablet drop magazine

Example Runtime Report

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PTA DISSOLUTION TEST INSTRUMENT TYP PTWS300 S/N: 10710
Product: Muster                               Batch: 007
Start Test: 04-19-2002 15:48                 Test End: 04-19-2002 15:54
Nom. Speed: 50 rpm                           Nom. Bath Temperatur: 37.0 °C
pH Meter: not activated                       Test-Start Condition: all correct
Operator: PT
Info: Test

Wait for Corr. Par.: 04-19-2002 15:48

1. Start rpm: 50      Temp: 37.0 °C      04-19-2002 15:48
2. Interval 1: 2min 04-19-2002 15:49
   rpm: 50      Temp: 36.9 °C
   T1: 36.5    T5: 36.2
   T2: 36.2    T6: 36.4
   T3: 36.4    T7: 37.0
   T4: 37.0    T8: 36.3

3. Interval 2: 2min 04-19-2002 15:51
   rpm: 50      Temp: 37.0 °C
   T1: 36.8    T5: 36.2
   T2: 36.2    T6: 36.7
   T3: 36.7    T7: 37.2
   T4: 37.2    T8: 36.5

End Runtime-Report ERRORS: 2
    
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Technical Data (Standard Version)

Parameter	Specification
Display	6"- 320*240 Pixel LCD, illuminated in monochrome
Data Entry	Alpha-numerical and 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 Descriptions	Unlimited number of different test descriptions can be file
User Access Control	Dual Level access control, password expiry date control
OQ, PQ control	Programmable time periods to remind on 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
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 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” heater 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 Requirement	112 x 58 cm
Packaging	137 x 88 x 78 cm (W x D x H)
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.

