PTWS 830

USP/EP Tablet Dissolution Testing Instrument

PTWS 830 is an 8 position, 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>.

User Friendly Interface and User Management System

PTWS 830 is equipped with a wide 7-inch color touch screen, designed to enhance usability. The user interface incorporates rich graphical elements, smooth animations, and clear explanatory texts to guide users through every function. The flexible user management system allows for the inclusion of an unlimited number of users, ensuring secure and customized access. Additionally, the system supports an unlimited number of test methods, providing adaptability for a wide range of laboratory needs.

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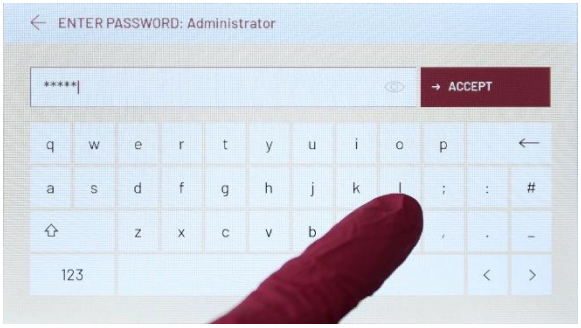
Regulatory Compliance and Audit Trail Features

The audit trail system records all events and changes within the instrument, providing a detailed account with both before and after information, fulfilling the regulatory requirements of 21 CFR Part 11. The audit trail can be filtered using criteria such as date & time, user, method and type of event.

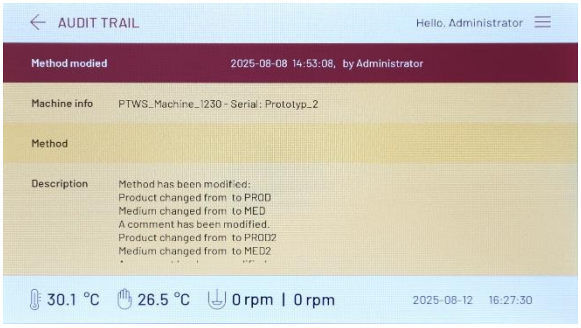


Instrument Design for Ease of Use and Reliability

The instrument head features a robust housing constructed from powder-coated stainless steel, ensuring exceptional durability and ease of cleaning. Integrated into the head is a 7-inch touch display, protected by a solid glass plate. This design not only offers a sleek appearance but also provides reliable protection for the display in demanding laboratory environments.

Convenient Water-Draining Design

The water bath is designed for convenient emptying and efficient cleaning. The tap connection has been enhanced for increased stability and repositioned to optimize drainage, facilitating more thorough removal of water. Additionally, both the cover and the water bath are removable, allowing for detailed and intensive cleaning when required.

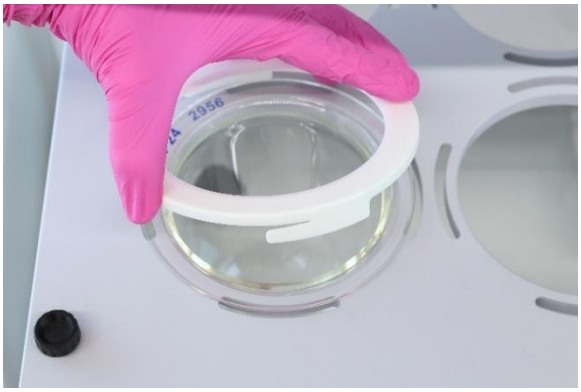


Touch Screen Operation

All instrument interactions are carried out via a capacitive touchscreen interface, engineered to remain highly responsive even when operated with laboratory gloves. This design not only enhances user convenience but also supports strict hygiene standards in laboratory environments.

Quick Connector System

The Plexiglas water bath features a quick-connector system ensuring secure, leak-free attachment of the heater module to the water bath.



Convenient and Precise Electronic Lifter System

PTWS 830 is equipped with a centrally located electronic lifter. It offers the ability to program up to 16 working positions. For models equipped with the EPE automated sampling system, up to 16 sampling positions can also be set, including a dedicated position for cleaning.

Temperature Sensor and Probe

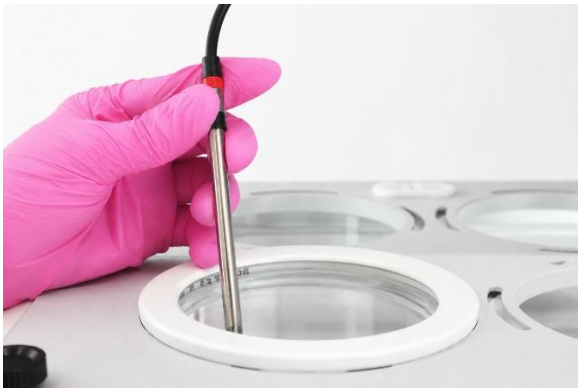
In addition, an external temperature probe is provided for monitoring the temperature within the vessels or the water bath. The heating system's safety is maintained through an array of internal temperature sensors positioned at both the inlet and outlet of the heater, as well as a resettable thermal cutoff switch.

Sturdy Water Bath Cover System

The water bath cover is constructed from protected Aluminum, offering dimensional stability. Dissolution vessels are inserted into rings fixed to the water bath cover and secured using centering rings equipped with a 3-way bayonet catch mechanism.

Heater and Circulation Pump Module Design

The pump and heater are combined into a single external module with a durable, powder-coated stainless-steel housing. The heater module's internal components have undergone significant advances, incorporating a fully self-contained heating system. This innovation removes the need for a control sensor inside the water bath, simplifying maintenance while ensuring precise and reliable temperature control.



MonoShaft Stirring Tools and Staggered Start
PTWS 830 uses the Pharma Test MonoShaft design with a main shaft and interchangeable tool heads. The shaft stays fixed in the instrument, keeping tool clearance consistent after initial installation. Each stirrer can be manually lifted for easy vessel access.

PTWS 830 also supports staggered start across its 8 positions, useful in manual mode.

Flexible Automation Capabilities

The instrument can be equipped with a variety of installation options:

EPE Automated Sampling System: This system enables automated and precise sample collection throughout the dissolution test. The sampling probes are automatically moved into the vessels during the sampling intervals.

Convenient Cleaning System for Sampling Probes and Tubing Lines
PTWS 830 is compatible with the popular cleaning system for tubing lines and the EPE automated sampling system. This cleaning system includes a plastic beaker designed to hold cleaning solutions and magnetic holders, which can be securely affixed to the underside of the TM tablet drop magazine. In this configuration, the probes of the EPE automated sampling system can be positioned within the beakers, enabling efficient flushing and cleaning of the system.

ITM Vessel Media Temperature Monitoring System: By monitoring vessel media temperatures at each sampling event, this system ensures that temperature conditions remain within required specifications during sampling and prior to the start of the test.

TM and TMA Tablet Drop Magazines: The manual or automated tablet drop magazines ensure the simultaneous drop of all samples into the vessels at the start of the test.

Offline Sampling and Sample Preparation Options

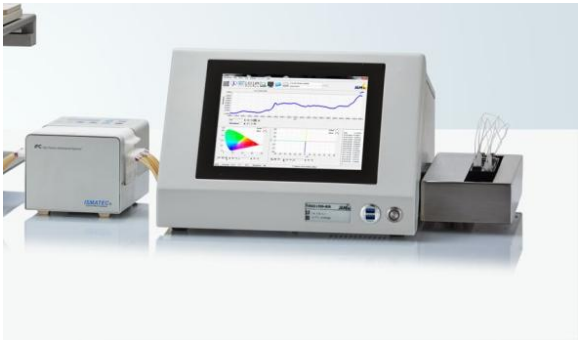
Using PTWS 830 within an automated system offers the operator full access to the vessels before and at the end of a run as the complete drive head is lifted electronically. Sampling sequence timing is programmed using the menu system of the PTWS 830 instrument, while sampling volume and the optional media refilling process are programmed at the fraction collector. The EPE automated sampling system is used to lower the sampling probes while sampling from 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 test process starts. If the refilling option is used media refilling will start automatically after a sample has been withdrawn.

Connection to DSR-M Dissolution Sampling Robot and PTFC Fraction Collector

For offline automation PTWS 830 can be connected to the DSR-M dissolution sampling robot. DSR-M features the capability of sample dilution and media refilling. It offers excellent sampling and refilling accuracy via the fully integrated valve-less piston pump module.

Alternatively, the PTFC-2/8SP fraction collector with PT-SP syringe pumps can be used. No external software is necessary to control either of these systems.

ADS-L Closed Loop Online Automated Systems using Diode Array Spectrometer



For an online automated closed loop system the J&M TIDAS L UV/VIS spectrometer with an 8-position multi-cell-changer is the ideal choice. This system is controlled by the powerful WinDiss ARGUS Dissolution software running on the integrated PC of the TIDAS L spectrometer.

The WinDiss ARGUS Dissolution software is a scientific dissolution data management software for instrument control, data acquisition, data management, processing and reporting – designed by users for users. Whether you perform dissolution tests occasionally or several times each day WinDiss ARGUS Dissolution will make you more productive in running tests and analyzing results.

PT-Node Network Adapter for Printing and Data Transfer

PT-Node is an adapter that connects up to two Pharma Test instruments simultaneously to a network using a wired LAN connection. This way you can print test results from the instrument via your web browser on any local or network printer. Furthermore, it is possible to transfer the test results from the instruments to external systems in the same network. PT-Node supports PTWS 830.

Example Runtime Report

RUN TIME REPORT	
==========	
PHARMA TEST PTWS 830	Model of the instrument
S/N: 22018	Serial number of the instrument
V: 1.00	Firmware version installed on the instrument
PRINT DATE/TIME:	
02.06.2018 12:31:48	Date and time of this print out
USER NAME: ADMIN	Name of the user currently logged in
PRODUCT NAME: PRODUCT1	Name of the product used for this test
METHOD NAME: METHOD1	Name of the method used for this test
BATCH: 1	Batch number entered at the start of this test
BATH TEMP NOM.: 37.0	Nominal bath temperature from the method for this test
BATH TEMP ACT.: 36.9	Actual bath temperature at time of the print out
LIFT: USP 1	Name of the lift position from the method for this test
VOLUME: 900ml	Media volume from the method for this test
DURATION: 0:10	Total duration time setting for the method for this test
SPEED NOM1: 50	Nominal speed setting from the method for this test
SPEED 1: 50	
SPEED NOM2: 100	First interval count
SPEED 2: 100	First interval delay
	Second interval count
I.-COUNT1: 1	Second interval delay
I.-DELAY1: 0:01	Third interval count
I.-COUNT2: 1	Third interval delay
I.-DELAY2: 0:02	
I.-COUNT3: 0	
I.-DELAY3: 0:00	
	Status of the test, if test is still running it will be
TEST STATUS: NO ERRORS	"IN PROGRESS"
	Start date and time of the test
START: 02.02.2015 12:21:08	End date and time of the test (if already finished)
END: 02.02.2015 12:31:08	
	Occurrence of first interval
INT.1:	Date and time of first interval
02.02.2015 12:22:08	Actual bath temperature when first interval occurred
BATH TEMP ACT.: 36.8	
	Occurrence of second interval
INT.2:	Date and time of second interval
02.02.2015 12:24:08	Actual bath temperature when first interval occurred
BATH TEMP ACT.: 36.9	
	If no intervals have yet occurred, it will be "NO INT"
OPERATOR NAME	
.....	Space to write down name of the operator
SIGNATURE	
.....	Space for the operator's signature

Advantages

» Integrated audit trail ensures 21 CFR Part 11 regulatory compliance
» Flexible user management system with unlimited number of users ensures secure access
» The modern user interface is easy to use and quick to learn
» MonoShaft™ stirring tool design avoids re-adjustment of immersion depth after tool exchange
» Secure and easy to use vessel centering system with bayonet catch
» High flow-through water circulation system for quick heat-up and optimal temperature distribution
» Automatic lift-up at the end of a test for quick access to all vessels
» System is easy to clean thanks to the optimized water bath design and cleaning system for the tubing lines (optional)
» Wake-up functionality to start heating at a pre-programmed time to reduce waiting times
» Staggered start feature for convenient manual sampling
» Automatic stirrer stop when instrument head is moved
» Modular design to minimize bench space requirements
» IQ/OQ documents included free of charge

Features

» Fully USP <711/724>, EP <2.9.3/4>, BP, DAB and JP <15> compliant
» 8 stirred vessel positions in a 4+4 arrangement
» Centrally located electronic lifter for instrument head with 16 programmable working positions
» Low-evaporation vessel covers with silicone inlay
» Staggered start capability for all testing stations
» Programmable infinity test
» High flow through water circulation design
» Method management and user administration
» Audit trail recording all events and changes with before and after information
» Control of peripheral instruments such as DSR-M Dissolution Sampling Robot or PTFC-2/8SP fraction collector
» Optical and acoustic signals to inform about sampling intervals, timer count down function
» Integrated calibration programs with PQ interval warning

Standard Scope of Supply

PTWS 830 comes ready to use with the following standard scope of supply:

» One set of 8 MonoShaft™ stainless steel stirrers and USP App. 2 paddles
» One set of 8 individually coded 1,000ml borosilicate glass dissolution vessels
» One set of 8 vessel centering rings with bayonet catch
» One set of 8 low evaporation vessel covers with silicone inlay
» One set of 8 depth adjustment balls
» One external temperature probe for water bath and vessels
» One bottle of ALGEX Magenta water preservative
» Comprehensive documentation set including:
  › User manual
  › DQ/QC instrument compliance test report and certificate
  › IQ installation qualification document
  › OQ operation qualification document
  › Instrument logbook
  › Compliance certificates for vessels and stirring tools

Instrument variants

In addition to the standard instrument design, PTWS 830 is also available in these model variants:

» PTWS 830-2 2-liter dissolution vessel version (can also be used with 1-liter vessels)

Installation Options

These options can be installed in the factory to enhance the usability of the instrument:

» EPE-830 automated sampling system that automatically moves stainless steel sampling probes into the programmed sampling position at the programmed intervals
» TM-830 manual tablet drop magazine to ensure simultaneous insertion of up to 8 samples
» TMA-830 automated tablet drop magazine to ensure simultaneous insertion of up to 8 samples
» ITM-830 individual temperature measuring system to automatically measure the vessel temperatures of all 8 vessels before test start and during sampling

Accessories and Options

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

» Full range of MonoShaft™ stirring tools available: USP/EP apparatus 1, 2, 5, 6 tool adapter, cream cell, transdermal patch tools, each tool individually coded
» Amber colored vessels, individually coded for UV sensitive test materials
» 250ml MiniVessel set incl. mini paddles
» Cleaning system for sampling probes and tubing featuring magnetic holders
» Ticket printer
» PT-Node network adapter
» Full range of certified validation tools available

Technical Specifications

Parameter	Specification
Compliance	Fully USP <711/724>, EP <2.9.3/4>, BP, DAB and JP <15> compliant
Number of stirred vessels	8 (4 by 2 arrangement)
Stirring tool design	MonoShaft™ stirrer design
Stirrer speed range	25 - 250 RPM
Stirrer speed accuracy	±2% of set speed, typically < 1%
Stirrer shaft wobble	Better than 0.2 mm total run out
Heating system	Heating and circulation pump module
Heating range	25.0 – 45.0°C
Heating accuracy	± 0.2°C inside the water bath
Display & date entry	7", 1024x600 pixel resolution color LCD touch screen, backlit
Audit trail	Integrated, logging all events and changes with before and after information, multi-level filtering
User management	Unlimited number of users with password and user rights
Working positions	16 programmable stirrer immersion positions (paddle over disk, transdermal cylinder etc.)
Sampling positions	16 programmable sampling probe immersion positions including a cleaning position
Method management	Unlimited number of methods
Timer	Programmable sampling times, wake-up and sleeping mode, operation time information and timer count-down mode
Acoustic signal	Programmable acoustic signal for operator information
Calibration & PQ control	Built-in calibration programs with OQ/PQ interval warning
Printer support	External ticket printer or PT-Node network adapter
Interfaces	CAN port for remote control, RS-232 port to connect serial devices, I/O port for remote control of external instruments in automated systems, like DSR-M and PTFC
Instrument dimensions	Bath: approx. 75cm x 45cm x 75cm (width x depth x height) Heater: approx. 22cm x 32cm x 22cm (width x depth x height)
Net / gross weight	Approx. 75 / 130 kg
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.