

ADS-L 1220

Fully Automated Tablet Dissolution Testing System

The online dissolution system ADS-L 1220 consists of a Pharma Test dissolution tester PTWS 1220, the DAD UV/VIS spectrophotometer TIDAS L and a multi-channel pump. The system is controlled by the 21 CFR Part 11 compliant user friendly WinDiss ARGUS dissolution software. All instruments are compliant to regulations from USP/JP/CP/EP/USFDA/ASTM and come with a 2 years warranty. One company is responsible for the support of all components.



The PTWS 1220

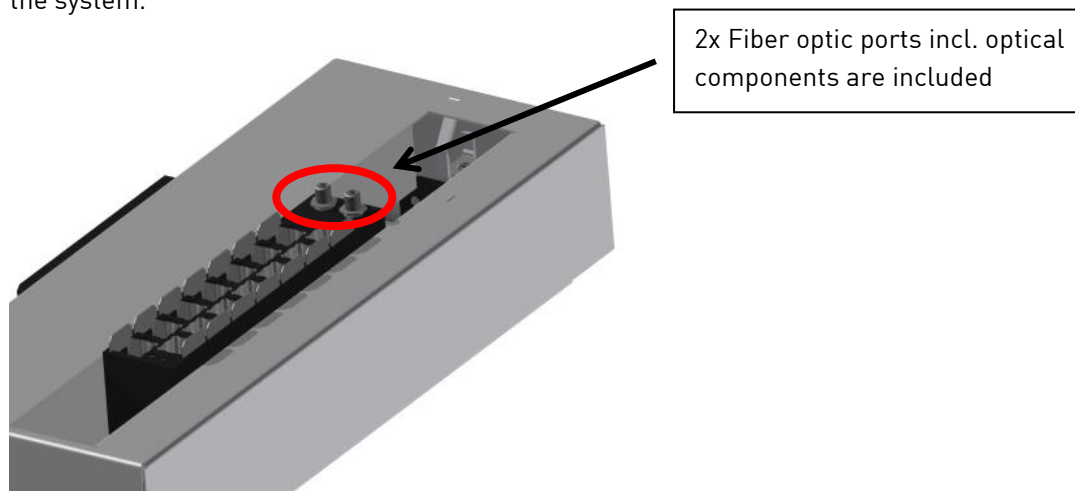
The PTWS 1220 is a 6+6+2 position 6-by-2 dissolution bath with an automated lift system for the instrument head. An automated sampling manifold EPE is used to perform dissolution tests as per USP Apparatus 1, 2, 5 and 6. Each 316 stainless steel tube which is part of the EPE sampling system can be equipped with in-line filters to avoid the transfer of undissolved particles into the measurement cells of the spectrometer. The tablet magazine includes magnetic holders for the tube cleaning device.

The TIDAS L DAD Spectrometer with Cuvette Changer

J&M’s latest models of laboratory spectrometers, the TIDAS L series of diode-array spectrometers, follow an approach of integration. The diode array technology gives you rapid results over the full spectrum with each measurement. It feature an integrated Windows based PC with a large, high-resolution touch screen running the WinDiss ARGUS and the additional spectrometer software TIDASDAQ3. By integrating the PC into the spectrometer unit the TIDAS L instruments make excellent use of the limited bench space in today’s typical laboratories. The instruments can also easily be connected to the company’s network.

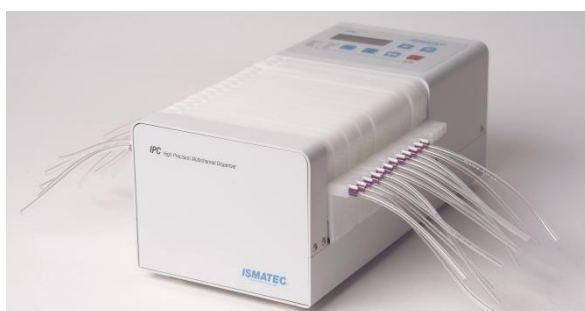


Furthermore, the TIDAS L spectrometers feature an additional E-ink display which acts as a smart type plate. It shows data like your lab asset or inventory number, the date of last calibration or the due date of the next calibration. Due to the unique nature of the E-ink displays, this information remains visible even when the instrument is turned off. This makes it easy to assess the condition of instrument at a glance. The light in the TIDAS L is transferred over solarization resistant fiber optic cables from the light source to the detection system. No parts are moving in the light path which gives a very high robustness, reproducibility and stability compared to scanning spectrometers. The use of certified optical fibers in combination with optimized measuring cells ensures reliable measurement results. The picture below shows the 14-cell changer with 2 additional ports for fiber optic probes. The fiber optic channels can be used to get more detailed information about the dissolution process. All optical parts for these 2 additional channels are included. Only fiber optic probes needs to be added to the system.



The TIDAS L is the perfect spectrometer for dissolution online tests:

- » Very fast measurements of the complete spectra. 14 cuvettes are measured in about 15 seconds.
- » More information due to the availability of the complete spectral data results in a higher robustness. Other wavelengths and wavelength ranges can be used to perform scattering and turbidity corrections.
- » Multicomponent analysis can be performed easily with a Diode Array spectrometer. Interval times remain very short.



The Multi-Channel Peristaltic Pump

The IPC Pump is a very well-known multichannel pump which is suitable for online dissolution measurements. It is used to transfer the dissolution media in a closed loop from the vessel to the spectrometer and back to the vessel.

WinDiss ARGUS Software

WinDiss ARGUS is a revolutionary scientific dissolution data management software tool for instrument control and advanced data acquisition, management, processing and reporting – designed by users for users. Whether you perform dissolution tests occasionally or several times each day WinDiss ARGUS will make you more productive in running tests and analyzing results. WinDiss ARGUS simplifies how you collect and report dissolution test results by letting you choose the analysis template that matches the way you work. Whether you are in a QC department concerned about data security, compliance and validation, or need maximum flexibility in the R&D area, WinDiss ARGUS can help your lab to perform more efficiently. Intuitive wizards help anyone in your lab work better – your next dissolution test is running in just a few clicks.

Bringing you faster to reliable results:

- » Access dissolution data quickly using relational database technology
- » Correct turbidity in your spectra at a second wavelength or by second derivative
- » Analyze multi component drugs with models created by CAMO's The Unscrambler
- » Drives spectrophotometers, baths and accessories of the market leaders
- » Controls offline sampling, online measurement, fiber optics and even multiple baths systems
- » Allows seamless growth from single workstations to a dissolution laboratory network
- » Designed for a data-secured regulatory lab environment

Tubing Connection

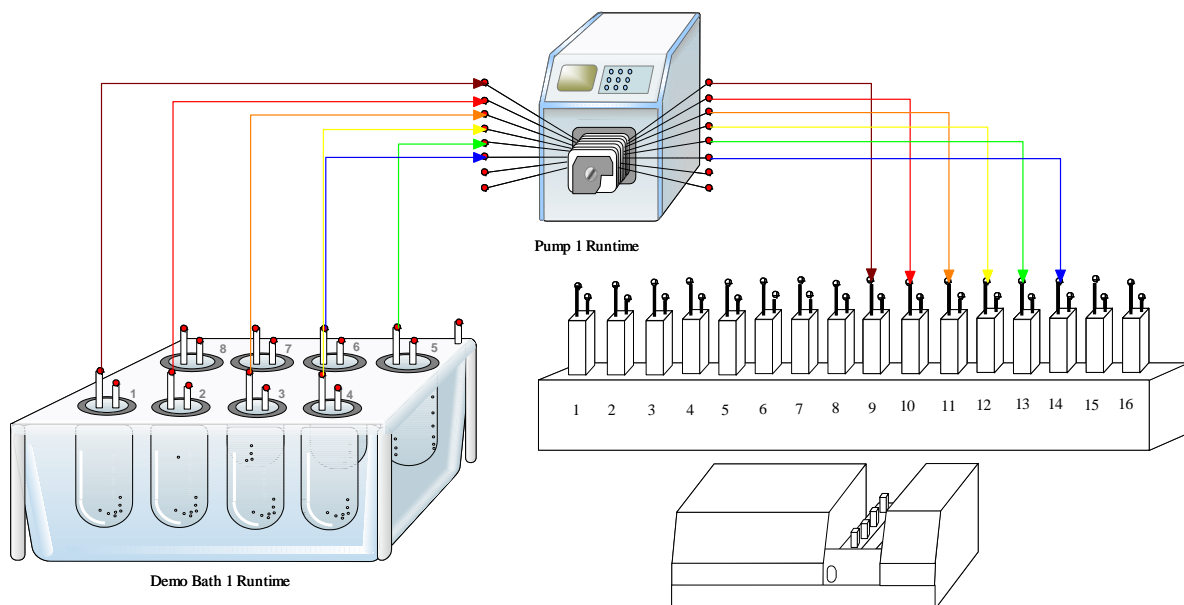
The tubing is made out of inert Teflon (PTFE). PTFE has been shown to be suitable for most of the APIs. The IPC pump tubing itself is made out of suitable inert "Pharmed" tubing.

High Quality Cuvettes

We only use high quality flow-through cuvettes which are designed for dissolution tests. Most important is the material and the accuracy of the path length. Pharmacopoeia recommends having a path length tolerance of at least $\pm 0.005\text{cm}$. Path lengths of 10mm down to 0.1mm are available in accordance with USP and EP. According to the law of Lambert Beer the decrease of a path length from 10mm to 1mm is equal to a dilution of 1:10. Therefore smaller path lengths are used in case the concentration of the product is high.

Principle Online Dissolution Testing System

The multi-channel IPC pump is used to transfer the media from the vessels to the spectrometer. The samples here are circulated in a closed loop, so that there is no sample volume loss over the time of the dissolution test. At the programmed time point the sample circulation is stopped and either a single point absorbance reading or a full UV/VIS spectrum of each vessel is collected. The control of the entire system as well as the data handling, calculation and reporting is performed by the 21 CFR Part 11 compliant WinDiss ARGUS Software.



Advantages

- » Automation for optimization of laboratory processes
- » Offers unattended operation after start of dissolution run
- » Full spectral data in milliseconds
- » Multicomponent analysis with the TIDAS L 570 DAD UV/VIS spectrometer
- » Very short sampling time-intervals with the full spectral information
- » No media loss due to closed loop design
- » Pharma Test takes full system responsibility
- » Hardware IQ/OQ documents included free of charge

Features

- » Sampling, measuring, and result calculation are automated
- » Online, closed loop system with integrated spectrometer
- » Systems composed of Pharma Test PTWS 1220 dissolution bath, J&M TIDAS L 570 DAD UV/VIS diode array spectrometer and IPC peristaltic pump
- » Controlled by WinDiss ARGUS PC software
- » Easy and effective cleaning procedure



Standard Scope of Supply

The **ADS-L 1220** comes ready to use with the following standard scope of supply:

- » TM-1220 manual tablet drop magazine
- » EPE-1220 automated sampling system
- » Cleaning system for tubing lines with magnetic holders
- » 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
- » The TIDAS L 570 DAD UV/VIS Spectrometer
- » Cuvette changer with 14 positions + 2 additional ports for fiber optic probes
- » Integrated Windows PC with large touch screen
- » E-Ink display as “smart type plate”
- » USB and Ethernet ports for data transfer
- » Diode-array detector (DAD) for ultra-fast measurements of the complete spectra
- » TIDASDAQ3 software package for manual control of the spectrometer
- » 21 CFR part 11 compliant WinDiss ARGUS software for optimized dissolution test procedures
- » 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:

- » ITM-1220 individual media temperature monitoring system
- » TMA-1220 motorized tablet drop magazine
- » PT-RP80 serial report printer
- » 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
- » Different cuvette sizes, path lengths from 10 mm down to 0.1 mm

Technical Specifications ADS-L 1220

Parameter	Specification
Dissolution Bath	PTWS 1220 12-position dissolution bath
Spectrometer	TIDAS L UV/VIS diode-array spectrometer with 14 channel cell changer, 2 additional channels for fiber optic measurements
Spectrometer Specifications	Wavelength Range 190 – 1100 nm (Spectral resolution \leq 2 nm); Included light source: 35 W Deuterium/ 7,5 W Halogen
Pump	IPC 16 peristaltic pump with 16 channels; adjustable speed 2.5 – 50 rpm
Tubing	Color-coded full teflon-PTFE tubing to connect the system
Software	WinDiss ARGUS dissolution software package + TIDAS DAQ3
PC	Windows based integrated PC
Tubing Installation	Teflon tubing with stainless steel sampling probes
Sampling System	Resident sampling probes installed onto individual test vessel covers
System Dimensions	Approx. 2200 x 1000 x 1000 mm (Length x Width x Height)
Packaging Dimensions	Approx. 1370 x 780 x 870 mm (Length x Width x Height)
Net / Gross Weight	Approx. 120 kg
Certification	All instruments and components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All instrument IQ & OQ documents included (software IQ & OQ documents are available as options)

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

For more technical details see the individual instrument brochures as well.