Staggered or simultaneous stirrer start, manual or automated operation is offered by the advanced ADS-PTWS100 System. It includes an Ismatec Multi Channel Peristaltic Pump and a SA500 UV/VIS Diode Array Spectrophotometer or a Pharma Test T70 UV/VIS split beam UV/VIS Photometer with 8-cell changer or any other suitable spectrophotometer with multiple cell changer. The fully automated closed loop Tablet Dissolution Testing System is controlled by the WinDiss32 Software Suite which is fully 21CFR Part 11 compliant.

The PTWS 100 3by2 or 2by3 Lift-Up Dissolution Bath is equipped with insitu Sampling probes. Each sampling tube may be fitted with 5 or 10 micron in-line filters so as to avoid the passage of insoluble excipients into the measurement cells inside the spectrophotometer. The samples to be tested are dropped at the same time into the Dissolution Vessels for simultaneous sampling and measurement. Teflon tubing is connecting the Dissolution Vessels via an 8 channel Peristaltic Pump (IPC 8) to the Photometer with its built-in cuvette changer. All instruments are controlled by the WinDiss32 Software which has to be installed to a suitable PC.

As with nearly all sampling systems re-usable in-line filters are attached to the sampling tubes which are placed in the dissolution vessel during the entire test, distance and dimensions are according to the USP directive which states that the sampling point must be exactly half way between the dissolution medium surface and the top of the stirring tool (Paddle, Basket or TD cylinder). At the appropriate pre-programmed time the pump will be switched on and the sample tubing lines to the cuvettes are filled. The pump will be stopped and the spectra measured are transferred from the spectrophotometer to the WinDiss32

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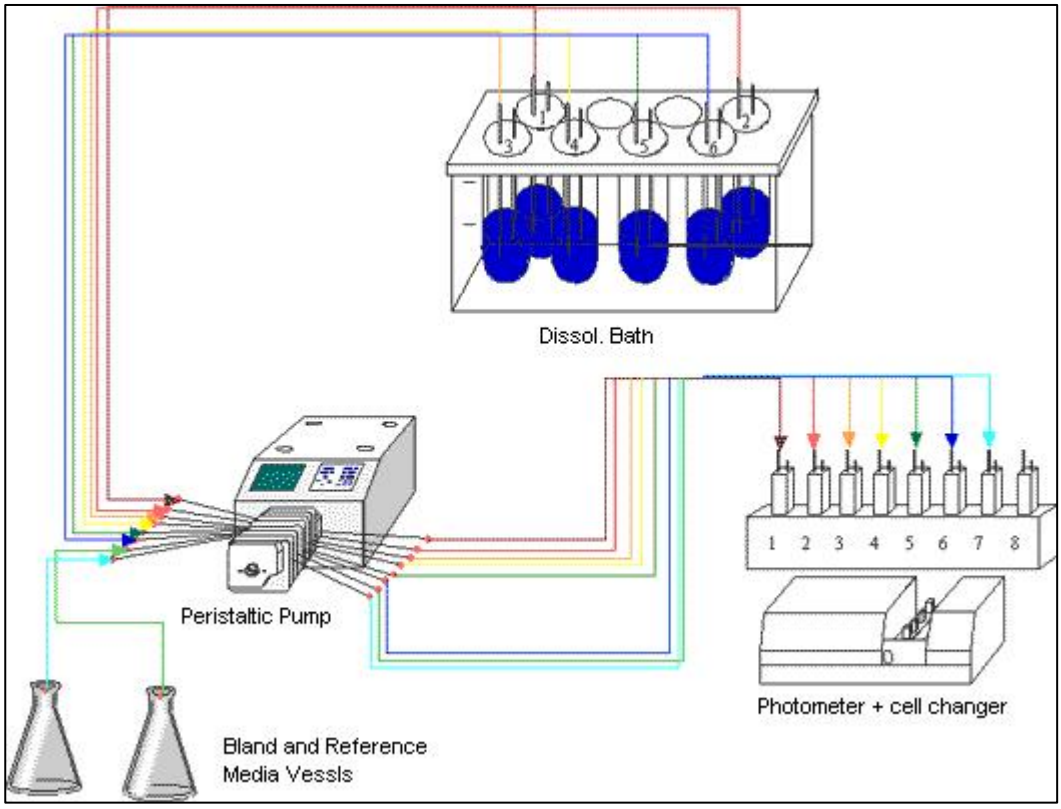
Software for further processing. Also stirring speed, bath and media temperature (optional), sampling and measuring time are logged.

As the PTWS 100 is fitted with 6 vessels, then cuvette 8 can be filled with a fresh Reference Standard and cuvette 7 is filled with Blank Media. One or both can be measured each time prior to the measurement sequence. This has an advantage in that minor variations in absorbance values encountered over a series of measurements can be compensated for as each set of measurements is made relative to a Reference Standard which has been treated in exactly the same way as the samples. At the end of the pre-programmed sequence, the dissolution / time profile as well as the final concentration of active in solution may be displayed or printed prior to storage.

Operating Principle:



On-line Systems

Using an automated Dissolution System is offering a good number of advantages, such user free sampling, on-line measurement of drug absorbance, accurate sampling timing, precise sampling positioning using an inside media sampling probe (insitu). Also data correction, using the on-line Standard and/or Blank Media and automated result calculation will save time and offer highest quality data presentation.

This popular configuration is elaborate, but allows real time calculation of results using the new fully 21 CFR Part 11 compliant WinDiss32 software and is by definition PC controlled. The overall structure of both software packages and their programming options is described in our WEB publication called: Dissolution Automation: **Key points for Consideration**

With this multi-cell changer configuration, the basic automation elements are entered into the program structure. This data, once installed will cause the software to further interrogate the user as to the configuration of the automation elements. Taking the spectrophotometer as an example, the program needs information as to whether there is a cuvette changer or not and if so, then is it a 6, 8 way or even 16 way. This is vital information as the Blank Medium has to be compared to the reference cell, and zeroed at the appropriate wavelength. This is done on cell 7, 14 to 16 with an 8- or 16-cell changer as this positions are usually connected to the Blank Media Vessel. The Standard Media (for concentration calculation) is usually in cell 8 or 15 to 16. This means that the medium can be compared to the reference cell and zeroed at the start of each measurement sequence. After the zero has been established the measurement sequence is then cell 8 (Reference), followed by cells 1 to 7 or to 16.

What is an ADS-PTWS100 system?

The ADS system offers an auto dissolution package incorporating validated systems. A state of the art Dissolution Bath Type PTWS 100 with 6 vessels and insitu sampling probes. A Pharma Test T70 UV/VIS split-beam Photometer or a PDA Diode Array SA500 Diode Array UV/VIS spectrophotometer, or a suitable spectrophotometer of any other branch possible to be connected into the system if equipped with 8-cell changer, 8 channel peristaltic pump equipped with Ismaprene pump tubing. Teflon based sampling systems which are transferred from the vessels via the peristaltic pump to the spectrophotometer and the inside flow cells and back to the vessels (closed loop). There will be no cross-contamination or volume loss due to the individual closed loop system design.

The flow cells which have to be used are available with different path length to suit your measurement needs. Depending on the maximum concentration you will be able to use cells from 20 mm path length (SA500 only) down to 0.1 mm which corresponds to a dilution factor of 1:200 compared to a manual sampling procedure.

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The Photometer

We offer different Spectrophotometer Drivers which may be incorporated into the ADS-PTWS100 Auto Dissolution Test System. Depending on the application the system should be used for, the user may select between single beam and double beam Photometers or Diode Array Detectors.

The use of a single or double beam spectrophotometer is possible if only single or multiple wavelength tests with now timing problem have to be performed. As soon as measuring speed or spectra scanning should be done we recommend the use of a PDA Diode Array UV/VIS Spectrophotometer.

Any of the possible Spectrophotometer Types which can be included needs to be equipped with a 6- to 8-cell changer. The cell compartment should have enough space to connect the required Tubing and allow free movement of the cell changer during operation.

The SA 500 Diode Array Spectrophotometer

If a SA 500 Diode Array Photometer is included into the system all major components are made and supplied by us which mean trouble free and reliable operation during the full live cycle of the system. The SA 500 has a built in 8-cell changer (16-cell optional). The cell changer compartment is not covered and is therefore easy to access. Thanks to the cell holder design, all of the installed UV cells are correctly positioned in the light path. The use of fibre optic light transmission allows an optical system design without moving parts. A fibre optic beam coupler eliminates the requirement for mirror switching at the light source (change from D_2 to Tungsten lamp) as found in conventional spectrometers. The overall result is improved reliability and long term system stability.

The cell holder will take flow-cells with a maximum path length of 20 mm as well as common 10 mm cells with a path length down to 0.1 mm.

The specially developed fibre optic technology used in the SA 500 is combined with a unique diode array detection module to give a unit which features very low energy losses compared with conventional optical systems.

These higher energy levels permit more rapid scanning of the array than is found in more conventional detectors resulting in a much faster scanning capability for a given signal to noise ratio. This is the only technology which allows real time data acquisition of complete spectra at very high speeds, e.g. in ≈12 milliseconds.

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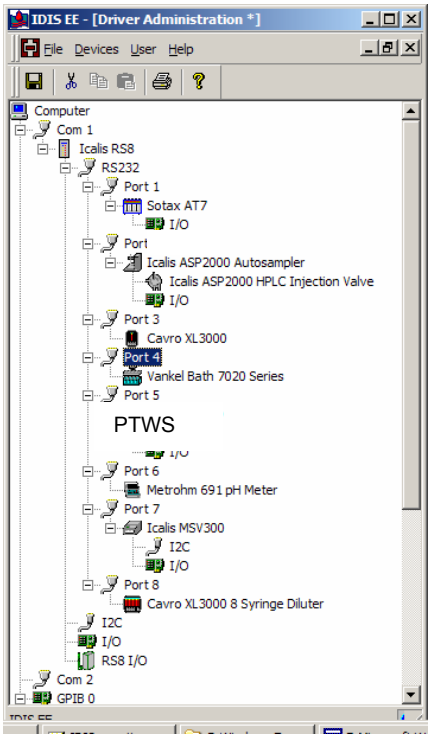
WinDiss32 Software

The CFR 21 Part 11 compliant WinDiss32 software drives the system and collects the results. It includes system operation log file, audit trail, user access right administration, password protection and administration, electronic signature, report generator etc. It offers single or multi-component analysis.

The ADS System components are controlled and integrated into WinDiss32 Dissolution Data management software which is used by the worlds largest Pharmaceutical companies.

Driver Linkage with Unique Solution Path Technology



- WinDiss32 Supports a wide range of Baths, Auto Samplers, Fraction Collectors, Pumps, and other Detectors
- It uses a Unique Solution Path Technology
- Configuration for different analysis requires no additional reprogramming.
- Support for Closed and Open Loop for UV and HPLC systems.
- WinDiss32 can operate with USP I, II, III and IV methods.
- Expanded capability for HPLC
- Collect and store samples in Auto Samplers to perform online dilution, mixing and measurement on the ADS.

Data collection rate:

The user can enter multiple data collection times during the entire dissolution run thus allowing more data points when active dissolves quickly and less towards the end of the profile.

FDA 21 CFR part 11 Compliance

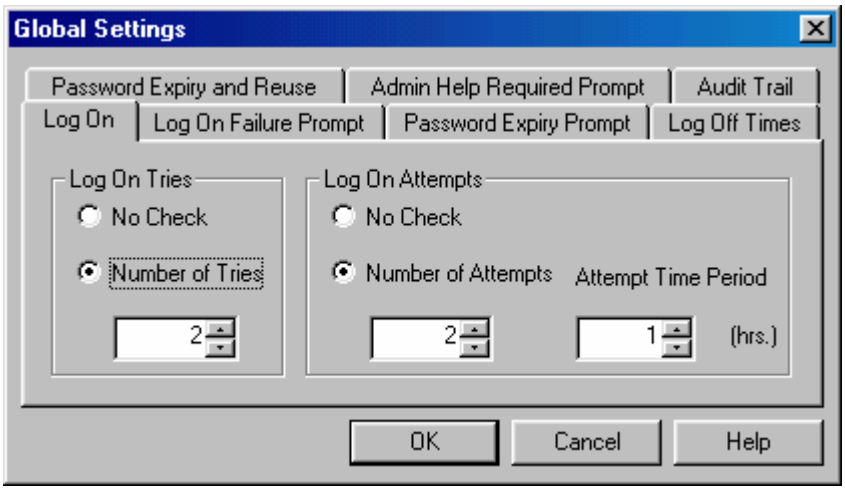
The WinDiss32 Administration allows the system administrator to enter details of users to access the system. The user Logon name, full name and password are configured for each user with Group or individual access rights.

Individual access to the system is by a unique user name and password and the users full name is displayed whenever the user logs on successfully.

Configurable Centralised Security

The Global Settings allow the administrator to set limits to prevent unauthorised access to the data station, Password Expiry, Log Off Times etc for each Access Level.

These activities can be performed remotely from any WinDiss32 networked workstation.



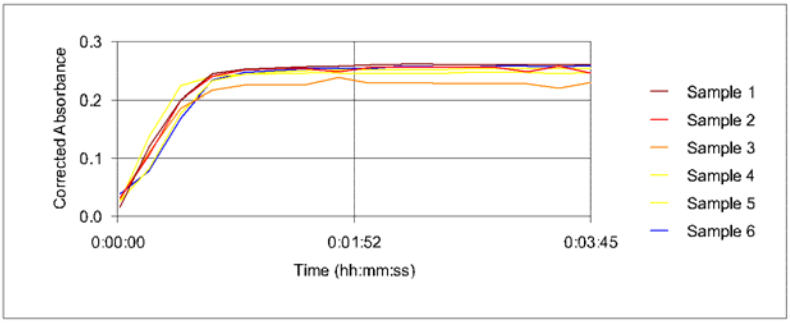
WinDiss32 provides the user with total management of the signing process, from start to finish. This includes configuring the number of signing levels, the Users for each level, Signer Activity and Meaning.

Signing and Reporting Signed Records

Once data is acquired in a Group with signing rights, any report generated will show the signing status for all pages of the record shown on the report.

Product Name	: Acetomenophen 250mg
Method Name	: Stability Test
Batch ID	: 12345
Method Group	: Form. 1
Batch ID	: 4567
Method Group	: Form 2
User Name	: John Brown
Group Name	: Quality Control
Station Name	: SALESXPLAPKEITH
Date - Time	: Thursday, September 30, 2004 16:04:37
Data Key Field	: 15
Data Occurrance	: 1
Data Unique ID	: 5F82AA10-0E1F-468A-8614-117C7DF3C513

	Sample % Dissolution.								
	Form. 1					Form 2			
Time (hh:mm:ss)	Sample 1	Sample 2	Sample 3	Mean	S.D.	Sample 4	Sample 5	Sample 6	Mean
0:00:00	6.21	12.03	12.41	10.22	3.48	10.47	9.70	15.13	11.77
0:00:15	46.55	41.12	42.67	43.45	2.80	31.81	53.15	30.65	38.53
0:00:30	77.59	77.59	72.16	75.78	3.14	68.66	86.90	65.56	73.71
0:00:45	95.04	93.49	84.18	90.91	5.87	90.39	93.10	90.78	91.42
0:01:00	97.76	97.37	87.28	94.14	5.94	94.66	94.66	95.82	95.04
0:01:15	98.92	98.53	87.28	94.91	6.61	96.21	95.04	96.98	96.08
0:01:30	99.70	98.53	87.67	95.30	6.63	96.98	95.43	98.15	96.85
0:01:45	100.09	96.21	92.33	96.21	3.88	97.37	95.43	98.92	97.24
0:02:00	100.86	99.31	88.84	96.34	6.54	97.76	95.04	98.53	97.11
0:02:15	101.25	99.31	88.84	96.47	6.68	97.37	95.04	100.09	97.50
0:02:30	101.25	99.31	88.84	96.47	6.68	97.37	95.04	99.70	97.37
0:02:45	100.86	99.31	88.45	96.21	6.76	98.53	95.82	99.31	97.89
0:03:00	100.86	99.31	88.45	96.21	6.76	98.15	95.82	100.09	98.02
0:03:15	100.86	96.21	88.45	95.17	6.27	98.15	95.82	100.09	98.02
0:03:30	100.86	100.09	85.34	95.43	8.74	98.15	95.04	99.70	97.63
0:03:45	100.86	95.43	89.22	95.17	5.82	98.15	95.82	100.47	98.15



Technician : Tested by John Brown 05/10/2004 09:50 Analyst Sign Off
Signing Level "Supervisor" Requires Signing.
Signing Level "Qualified Person" Requires Signing.

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Dynamic Report Editor

The WinDiss32 report organizer allows users to produce customized reports with the right information by selecting from a combination of objects such as Method Header, Data Tables, Method Parameters, Graphs and the Company Logo.

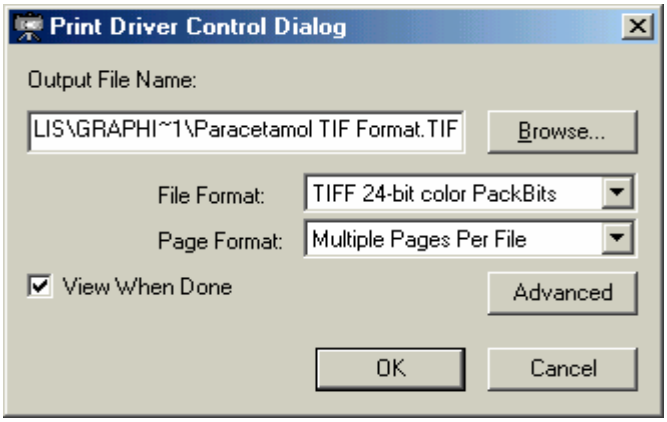
These details may include any parameter measured during the test such as Bath Temperature, Paddle Speed, Time Intervals as well as Absorbance, Concentration and % Dissolved.

Any number of pages can be selected with automatic page numbering.

Standard Report Format Graphics Printer

WinDiss32 is supplied with a Graphics Printer that provides compliance with 21 CFR Part 11 requirements for “human readable form”.

These reports can be circulated, emailed etc., in the safe knowledge that they are non-editable.



This Graphics Printer can capture any report into TIF, BMP or JPG (JPEG) and save them as electronic files.

The TIF format can save a multiple page report and the Image Viewer supplied automatically displays the printed file image for verification.

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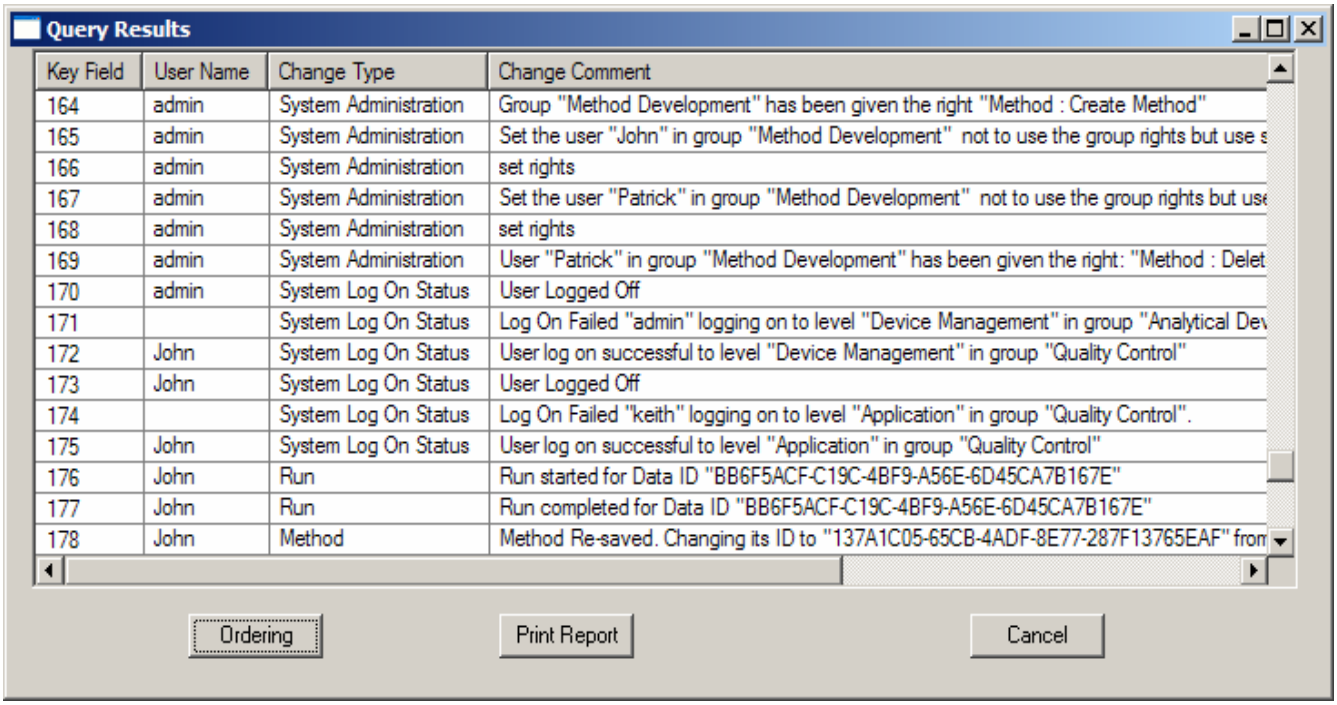
User Queryable Audit Trail

WinDiss32 Audit Trail lists all user activity that creates, deletes or modifies; i.e., from logging on and off to editing of method and data records.

This Audit Trail can be queried to limit the volume of information from a search and the results from any search can be printed.

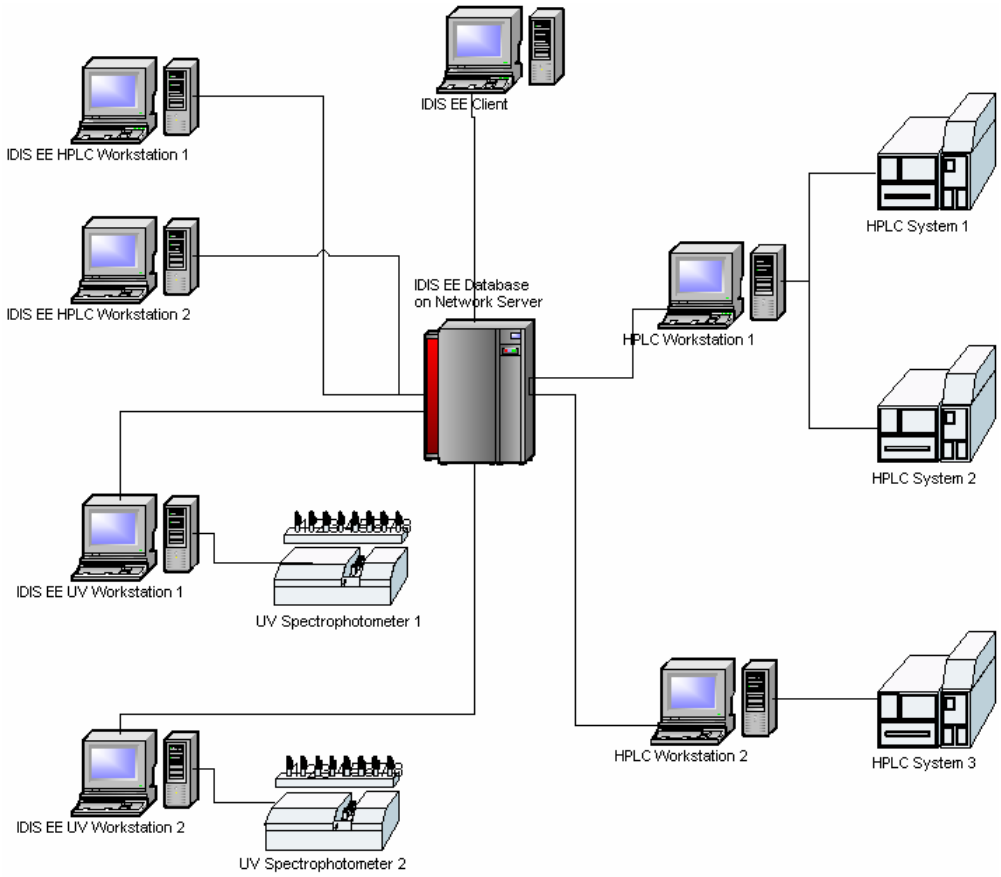


Networking

Our networked system provides a central relational database that contains all data (methods and data records) from all WinDiss32 workstations. Details are accessible from any station linked to the networked database.

Each system runs from a workstation PC, as each hardware configuration can be unique.

This configuration allows Data records to be signed remotely by users from clients. For example, it is now possible for analysts and supervisors or managers to view, sign, print etc away from the laboratory area.



Keeping the cost sensible….

We, at Pharma Test have opted to take the work out Spectrophotometer selection and accessory hunting by offering complete upgrade systems for existing Dissolution Baths which have not only differing degrees of sophistication but which also offer affordable options to cover all budgets.

Bath Drivers Available:

PHARMA TEST:	PTWS310, PTWS 100/600/1200, 610/1210 and DT series
Others:	Varian, Sotax, Erweka, Distek (ask for details and models to be included)

Photometer Drivers Available:

PHARMA TEST:	SA 500 PDA Diode Array Photometer incl. 8- or 16-cell changer - T70 UV/VIS Split-Beam Photometer incl. 8-cell changer
AGILENT:	8453 PDA Diode Array Photometer incl. 8-cell changer

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PERKIN ELMER:	Lambda 2/10/20 incl. 8-cell changer Lambda Lambda 25/45 incl. 8- or 16 cell changer
VARIAN:	Carry 50 incl. 8- or 18-cell changer
CECIL:	CE 2000, 3000, 5000, 6000, 8000 and 9000 series incl. 8-cell changer
JASCO:	UV 500 incl. 8-cell changer
BECKMAN:	DU 600, DU 7000, DU 9000 series incl. 8-cell changer
ANALYTIK JENA:	SPECORD incl. 8 or 16 cell changer
THERMO Scientific:	EVOLUTION, incl. cell changer

Technical Data of the spectrometer will be listed in the quotation

Pump Drivers Available:

Ismatec:	IPC 8, 16, 24
Watson Marlow:	PT-P80, PT-P160
CAT:	CAT 8/12 Piston Pump

Technical Data

PTWS 100 Dissolution Bath, 1 litre version

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Number of Stirring Positions:	6
Stirrer Speed:	Adjustable within 25-220 rpm, accuracy ± 1rpm
Stirrer Design:	Mono Shaft stirrers and stirring tool adapters. When immersion depths is set once no need to repeat when stirrer adapter has to be changed
Vessels:	Individually batch coded 1 litre USP/EP graduated glass vessels
Vessel Centring:	Auto-Centring System for each vessel by vessel covers
Thermostat:	External Heating System including circulating pump, spring loaded for vibration free operation and 1000 W heater, overheating protection, pump flow control
Temperature:	Adjustable within 25-45.0°C, accuracy ± 0.3°C
Wake Up:	Programmable wake-up time including heater start
Water Bath:	single piece blow moulded water bath with PP cover, built-in water diffuser for faster heating up times
Standard Supply includes:	6 stainless steel mono shaft stirrers, 6 stainless steel Paddle blades, 6 USP glass vessels, depth and centring gauge,
Sampling System:	insitu sampling probes including 10 micron PP sinter filter attached to each sampling ferrule
Tubing Installation:	Teflon Tubing using fast connectors, tube internal diam. 1.0 mm for low volume outside the dissolution vessels
Documentation:	Includes User Manual, IQ and OQ Documentation

CAT 8 Piston Pump

Ismatec IPC Pump

Peristaltic Pump IPC 8 channel

Pump Tubing:	Ismaprene ENE 021
Pump Speed:	adjustable, typical flow rate for dissolution approx. 5

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	ml/min
Accuracy:	depends on pump tubing, usually ± 5 % of volume rate
Pump Channels:	8 or 16
Interface:	RS232 or TTL
Documentation:	Includes User Manual, IQ and OQ Documentation

CAT 8 Piston Pump

Number of channels:	8
Pump head type:	200VCS
Material:	stainless steel, silent version
Stroke volume of pump head:	approx. 200 micro litre
Minimum flow rate:	0.15 ml/min.
Maximum flow rate:	20 ml/min.
Accuracy and precision:	< 1% over full range, excluding external factors such as tubing etc.
Pump connection:	1/4-28" UNF for PTFE connectors
Tubing:	1.0 mm ID, 1.6 mm OD PTFE/FEP (tubing not included) Rinse pump type HPLV 20V is included and is connected to all 8 pump heads
Interface:	RS-232 and I/O port
Documentation:	Includes User Manual, IQ and OQ Documentation

SA500 Diode Array Photometer

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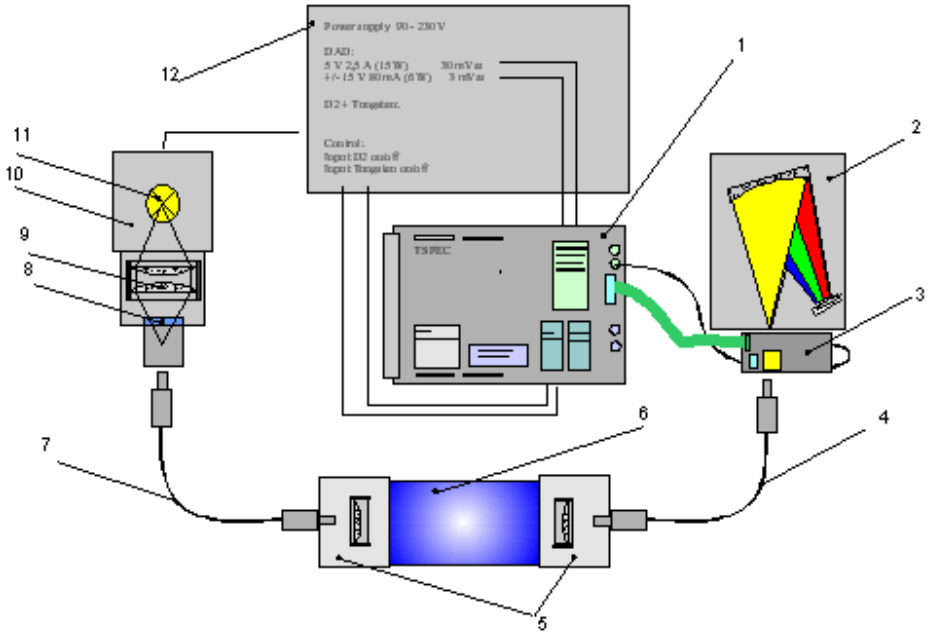
Optical System

Light Source	D_2 and Tungsten lamps
Lifetime:	D_2 lamp has a life of approx. 1500 hours
Wavelength Range	190 - 1020 nm
Maximum measurement speed	12 milliseconds / Spectrum
Number of Diodes	1024
Optical Grating	248L/mm
Spectral Resolution	0.8 nm/Pixel
Spectral Bandwidth	1.6 nm
Wavelength Accuracy	0.3 nm
Wavelength Precision	± 0.07nm
Noise (at 580nm)	± 2.5 x 10^{-5} AU
Baseline Drift	5 x 10^{-4} AU
Temperature Drift	< 0.005nm / °C
Scattered light:	< 0.1% @ 340nm (D_2 lamp)
Data Integration:	Data integration time approximately 100ms per channel
Flow cell compensation:	Work with either absolute or baseline corrected absorption data
Communication Port :	Ethernet and RS232
Multiple Cell Changer:	8 cells (max. path length 20 mm) or 16 cells
Flow Through Cells :	0.1 - 0.2 - 0.5 - 1.0 - 2.0 - 5.0 - 10.0 - 20.0 mm path length (not included in the supply scope)

Setup



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Electronic system

The SA 500 uses a very fast RISC Processor and processes the raw spectral data within the unit. All data storage and post processing is then via an external PC.

Documentation

Includes User Manual, IQ and OQ Documentation

WinDiss32 Software

- Design System components
- Create and file Testing Methods including instrument control data
- Program single ob multiple calibration data
- Select single or multi component analysis
- Read single, multiple wavelength or full scan
- File all data immediately after collecting (no information loss at all)
- Operate Single- or Dual Systems
- Includes User Manual, IQ and OQ Documentation needs to be ordered

Available ADS System Options

- Select other PTA Dissolution Bath or even use existing instruments
- Select other UV/VIS Spectrophotometer having multiple cell changer
- Operate 12 vessel or dual bath systems
- Include Auto Sampler for sample dilution or sample processing prior to injection and measurement

System Validation

System validation can be done using the USP Reference Standard (RS) Tablets and Standards. Supply scope includes full IQ/OQ documentation for the supplied hard ware.

Installation and Qualification

The dissolution system installation and qualification may be performed at installation by a Pharma Test trained engineer or agent. All IQ and OQ paperwork supplied as standard.

Powerful dissolution result reporting software to generate individual report sheets including both results and graphics.

WinDiss32 is installed under Windows NT or 2000, XP™ (GB or US Version)

Other factors influencing Dissolution Rates.

Below are some interesting statistics covering various things which may influence the results of a typical dissolution test run. Some influences are quite small but others, such as degassing the dissolution medium, are quite dramatic (ask for the PT-DDS Medium Degassing and Preparation Instrument brochure):

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Factors affecting the PQ results:

Type	Rating	influence degree
Temperature	not too significant	linear
Speed	**significant**	**10-30%**
Vibration	**significant**	**10-40%**
Centricity	reasonable	± 5-15%
Dissolved Gas	**significant**	**± 50%**
Media pH	reasonable	± 5-10%
Media Contamination	**significant**	**± 20-45%**
Sampling Position	not too significant	± 5-10%

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

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