



What is IDS 1000 In-Situ Dissolution?

IDS or In situ Dissolution System is about the application of direct measurement technology to Dissolution Testing. Traditionally, dissolution testing has been carried out on solid dosage forms using a standard dissolution tester. Samples of the dissolving active within the dosage form are taken for estimation from the dissolution tester either manually, or using more automated means such as a pump which has been connected to a suitable measurement device, usually a UV Spectrophotometer. Using IDS 1000, not only can the whole process of sample measurement be automated, but can also be self contained, such that there is no need for samples to be pumped out of the dissolution vessels to external measurement facilities such as a spectrometer, because all that is needed for the measurements to be made is contained within the confines of the instrument itself.

How does it work?

In the first instance the introduction of tablets or other dosage forms is as with a conventional dissolution instrument using a synchronous tablet drop magazine. The instrument is started according to the WinDiss32 Dissolution Software control, but the sampling sequences have been replaced by direct measurement technology within the dissolution vessel itself, with each measurement cycle accomplished in seconds rather than minutes.

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In-Situ Tablet Dissolution Testing - Type IDS 1000



The in situ measurement is carried out using fibre optic probes which are located in the shafts of the dissolution tools, i.e., a paddle or a basket (Apparatus 2 or 1). The fibre optic probe can be removed from the shaft so that various path length inserts can be employed for different active concentrations and extinction coefficient ranges. The fibre optic probe can then be simply reinserted into the tool shaft and the next analysis started.

Why is it different?

This system is different for many reasons and brings a really new dimension to dissolution measurement. For example the fibre optic probes are easily accessible and can have various cell paths attached. In situ probe placement means fast measurement times and no fluid circulation. No more pump tubing to be qualified or fail during a dissolution run. It also means that there is no fluid perturbation inside the vessel from sampling probes as used in conventional measurement cycles. It is also different from other instruments, in which attempts have been made to use fibre optic measurements, as this system has only one built in diode array spectrophotometer, but is still able to operate with 9 separate fibre optic sensor paths which are multiplexed to a central sampling unit. The biggest difference is that all IDS 1000 components, including the built-in Diode Array spectrophotometer are contained in a single housing, so that all optical components have a fixed geometry. This coupled with no externally pumped liquids not only allows us to

have very fast sampling sequences (useful for fast disintegrating and fast dissolving actives) but also means that the system does not contain unnecessary hardware, whilst still offering the advantage of a self validation routine (SST or System Suitability Test) for all the on-board measurement hardware. This validation routine is activated before the start of each analysis. The combination of self validation, speed, precision and no external fluid circulation are very attractive options. The built in Diode Array Spectrophotometer also means that single wavelength measurements are no longer made, but whole spectra may be accumulated to optimise the analytical wavelength used. This also allows the use of first derivative techniques in order to analyse multi-component formulations with overlapping absorption curves.

Design Features of the new IDS 1000 Technology

Today the instrument operator of such instruments expects not only conformity with the pharmacopoeia requirements, but also easy operation and accessibility to the test vessels. This means a dissolution bath should offer both good manual access as well as automation facilities.

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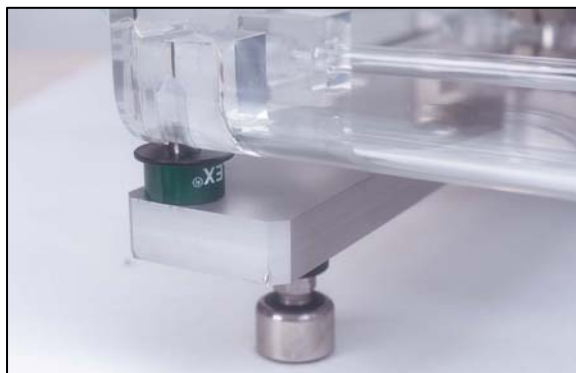


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The IDS 1000 offers both. All test vessels are placed in a 4 + 4 line-up so that it is easy to



remove spent samples and refill with medium. The clear-view Plexiglas water bath sits on vibration absorbing feet as does the built-in circulation pump. There are external temperature probes to better control both bath and medium temperature.

The special design, in which the pump and heating system (as well as the mains electronic boards) are accessible without having to move the instrument, coupled with the fact that the water bath is placed on vibration absorbers

virtually eliminates any vibration transfer and offers easy maintenance facilities. The built-in circulation pump is specially isolated for absolute vibration free operation. The measurable vibration is even lower than that of systems which use a separate heating circulator system that is placed to the same bench. The electronic control system monitors water level, pump flow, stirrer speed and temperature.

The depth setting of the stirrers is programmable. In fact 8 tool depth positions can be selected to meet all settings required for different test tools such as Paddles, Baskets, Transdermal Cylinders and so on.

The PHARMA TEST IDS 1000 In-Situ Tablet Dissolution Tester exceeds all technical requirements which are currently described in the USP <711/724>, FDA, EP <2.9.3/4> and German Pharmacopoeias.

How does the In-Situ Dissolution Test work?

= Works principally by making all of the measurements in situ

- No need to remove any samples
- No worries about USP 1% limit for volume inaccuracies
- All USP rules regarding sampling position followed
- Comes with USP/EP App. 2 stainless steel paddles
- Literature to support similar results to conventional testers
- Easy access to all user serviceable parts
- All IQ and OQ paperwork of the instrument is included in the standard supply scope

Fibre optic guides take the measurement to the sample (vessel)

- Fibre guides made from stainless steel
- Interchangeable tips for cell path variation
- All fibre guides plug into multiplexer input on front panel

Measurements made with hollow shaft technology

- 316 Stainless steel fabrication throughout
- Paddles or baskets just screw into mono shaft
- Paddle “windows” allow good flow through of medium

System set up to work with almost all USP tools

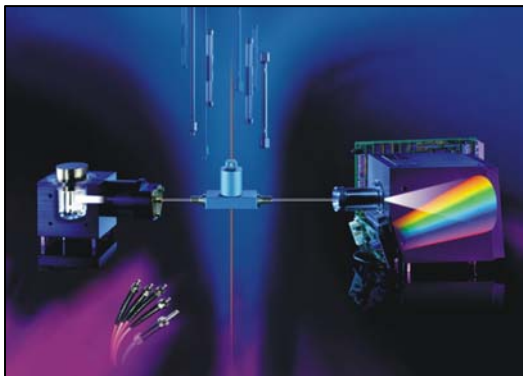
- Choose USP 1 or USP 2 as well as USP 5
- Special tools for trans-dermal patches and creams
- Easy tool change over
- Qualify the 25mm position for paddles and all other tools are automatically in correct working position.

Synchronous tablet drop with auto-magazine



- Program controlled tablet drop for all vessels while stirrers don't move
- Tablet magazine doubles as low-loss vessel cover
- Can hold oblongs as well as round dosage forms

UV measurements made using a DAD Spectrophotometer



- State-of-the-Art high performance DAD Spectrophotometer
- Built in multiplexer means only one spectrometer needed
- Excellent drift characteristics
- Easy access to all serviceable parts (e.g., lamps)

The IDS 1000 Tablet Dissolution Instrument offers:

- SST, System Suitability Test prior to the start of an analytical sequence.
- Easy access to heating/pump and power supply - without having to physically move the bath.
- Vertical and horizontal adjustment facilities for water bath, vessels, and stirrer drive.
- Mono stirrer shaft design, exchange stirring tools only
- Placement of water bath on vibration absorbers and special isolation assembly for the pump to ensure vibration free dissolution testing.

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In-Situ Tablet Dissolution Testing - Type IDS 1000

- Empty the water bath completely via the center drain tap
- Automated Tablet Drop magazine with incorporated vessel covers to stop media evaporation
- Clearly visible LCD screen shows actual operational status, “traffic light” display to highlight any errors.
- Visible and acoustic information informs the user of measurement sequences which take place in the instrument.
- Fully automated self check and re-adjustment of stirrer drive and bath thermostat as soon as any change has been detected.
- Programmable heater start up and shut down time.
- Vibration free water bath assembly, placed on shock absorbers, tough U-shaped bath and top bath frame design prevents damage and subsequent leakage.
- Very short bath pre-heating time and narrow temperature variations with tight temperature control due to new stainless steel, vibration free, water bath diffuser jet.
- Additional vessels to take either reference, standard or blank media
- Electronically controlled central pillar drive lifting device. 8 immersion positions are selectable to automatically set the correct tool height inside the dissolution vessels
- Built-in instrument log, which files all system changes as well as calibration data during the duty cycle of the instrument. This can then be downloaded onto any external printer.
- Calibration menu for stirrer speed, bath temperature, pH probe, stirrer immersion position etc.
- RS-232 interface for full external operation and instrument data transfer.
- Optionally available pH probe to read pH value of each vessel prior to, and after, a test run.
- Manual temperature sensor probe to read temperature of each vessel prior to and after a run; during operation the probe is placed into the reference vessel for continuous monitoring.
- OQ/PQ auto information, performance sequence programmable
- Short OQ available as instrument printout, additional to OQ supplied
- OQ warning on screen when OQ is due
- Log is printable on built in printer
- Bath and pump system on vibration-free mounts.
- Measurable vibration, less than 0.1 mil
- Plexiglas plate holding 8 cleaning beakers to be used to flush all shafts and dip probes when test is finished

Technical Data

- System Basis: IDS 1000 Dissolution Tester incl. hollow shaft stirrer shafts with exchangeable stirring inserts for paddles, baskets, transdermals etc
- Drive system: 24 V DC motor drive, microprocessor controlled continuous speed adjustment
- Speed Range: 25 - 250 rpm, ± 1 rpm
- Heating System: 1 KW heater with vibration free mounted circulation pump, inside bath stainless steel water diffuser
- Temperature Control: 1 control and one safety sensor, overheating cut-out and thermo fuse, external temperature probe to read media temperature prior and after test

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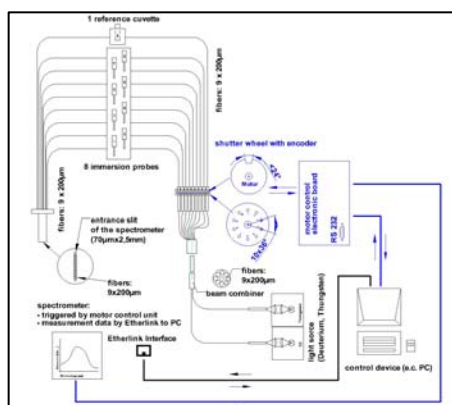
In-Situ Tablet Dissolution Testing - Type IDS 1000

- Temperature Range: 25.0° C - 45° C, ± 0.2° C
- Test Vessels: 8 round bottomed USP 1 litre glass vessels, individual numerical coding, 1 vessel for standard and 1 for medium (blank)
- Stirrers: 8 off 316 stainless steel mono-shafts with 316 stainless steel blades screwed into the mono-shafts
- Tablet Introduction: 1 automated magazine which drops 1 sample automatically at start of a run into the dissolution vessel during which time the stirrers are stopped
- Sample Analysis: UV Diode Array spectrophotometer incl. multiplexer to select 8 positions and a reference cell, wavelength range 190 - 610 nm, resolution 0.8 nm/Pixel; long term stability and wavelength accuracy <0.1nm; integrated Halogen and Deuterium lamp.
- Dip Probes: 6 to 8 fibre optic dip probes are placed inside the hollow stirrer shaft. Inserts are used to adapt path length from 1 to 20 mm
- Reference Cell: reference cell holder connected by a fibre optic link to the DAD Spectrometer: takes sample standard solution during an automated run
- Calibration Setup: 8 off 50ml plastic beakers are used to calibrate the dip probes when required. Simply place the holder underneath the stirrer and run a software controlled calibration procedure
- Control: Direct PC control, Windows 2000/XP
- Software: WinDiss32 IDS Dissolution Software, fully 21CFR Part11 compliant software package
- Validation: All instrument IQ and OQ paperwork available

Options IDS 1000

- ❖ Amber coloured vessels (for UV protection) - Instrument Calibration set for USP / EP OQ procedures
- ❖ Dip probes with different path length: 1 - 20 mm

Operating Principle of the DAD Spectrophotometer



A complete new design of detector and optics is implemented inside the IDS 1000 F/O Dissolution Test System. The result is a spectrophotometer which is optimized for the use of fibre technology offering state of the art performance. Combined with a 9-channel multiplexer it is possible to acquire 8 channels with fibre probes directly inserted to the hollow shafts of the vessels. The ninth channel allows reference measurement for each measurement cycle and boosts the instrument performance to a real double beam spectrophotometer.

are easily accessible.

It guarantees highest demands on robustness and reliability. The inbuilt solution inside the IDS 1000 reduces footprint and offers highest comfort for complete system validation.

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What are the key Spectrometer USP's?

- SST, System Suitability Test prior to the start of an analytical sequence.
- Easy access to lamp and power supply - without having to physically move the bath or the housing of the complete test equipment. Supports service and maintenance in an efficient way.
- Fast acquisition of all 9 channels in less than 20 seconds
- Real sequential dual beam operation with reference and intensity compensation
- Much higher response time, up to 50 times faster compared to existing systems
- A special highlight is the possibility of high speed kinetic measurements at a free selectable channel with up to 50 spectra per second.
- Fibre probes can be adapted or exchanged very easy
- No mechanical moving parts inside the active optical path, up to 10 times better drift and noise behaviour compared to competitive systems
- In-situ measurements reduce error impacts by sample transportation inside tubes and pumps.
- No additional space for photometer is required, the footprint of IDS 1000 includes all spectrophotometric components
- Fitted optical construction, calculated not "tried out", providing maximum light gain and thus outstanding signal to noise ratio and drift stability
- UV-resistant aperture adjuster and optimised light fibres, a nearly unlimited possibility to use various types of measuring cells or arrangements
- Multi-layer light filter to suppress second order effects
- High process stability due to ceramic housing with no moving parts for best thermal and mechanical stability, a guarantee for accurate and correct results
- Wavelength stability and reproducibility allows to measure absorbance values also at the slope of the signal. There is no necessity to measure always in the peak maximum.
- Easy handling, maintenance and service, no complicated and time-consuming calibrations necessary for simple validation
- Modern data processing allows unmatched measurement speed, easy setting of analysis parameters, saving time and money
- High acquisition speed offers fast channel multiplexing or high speed kinetic measurements
- Various interfaces like Ethernet, RS 232, ISA, PCI or PCMCIA available, providing maximum flexibility and future connectivity
- More than 16 year experience in the field of diode array detection in combination with fibre optics (in the spectral range of UV, VIS, NIR)

The Multiplexer unit

- State of the art design and functionality. Produces no additional noise or drift!
- The multiplexer wheel and the shutter are the only moving parts in the system
- The multiplexer can switch in less than 500 ms between each channel and can
- Address all channels in less than 5 seconds.
- Simple interface via RS 232 and full control by spectrophotometer
- Easy access for service by exchangeable components

Technical Data for the Measurement Instrument....

Diode Array Detector:	TIDAS Detector element with 1024 diodes
Spectral range:	190 nm – 610 nm
Spectral resolution:	0.8nm per pixel
Optical grating:	248 L/mm
Baseline noise specification:	Extremely low at < 50 AU peak to peak without smoothing
Wavelength accuracy:	Long term stability < 0.1nm Repetitive Accuracy is < 0.1nm
Temperature Drift:	< 0.005nm / °C
Scattered light:	< 0.1% @ 340nm (D2 lamp)
Light sources:	Integrated D2
Light source:	Built in light source with light transfer using fibre guides
Lifetime:	D2 lamp has a life of approx. 1500 hours
Data Integration:	Data integration time approximately 100ms per channel

Dimensions and Weights of IDS 1000 (all equipment included)

Bench space required:	110 cm x 80 cm bench space
Net weight:	aprox. 95 kg
Gross weight:	aprox. 135 kg

The WinDiss 32 IDS Software....

The DTS800 System is controlled and integrated into WinDiss32 Dissolution Data management software which is used by the worlds largest Pharmaceutical companies.

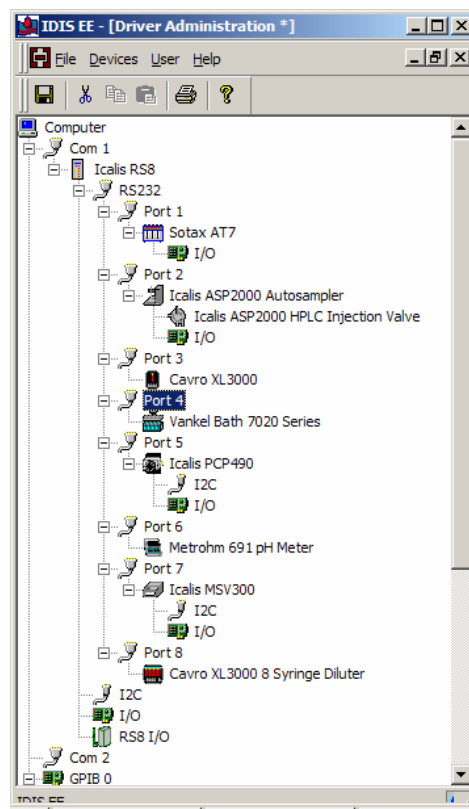
Driver Linkage with Unique Solution Path Technology

WinDiss32 Supports a wide range of Baths, Autosamplers and other UV/VIS 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.

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.

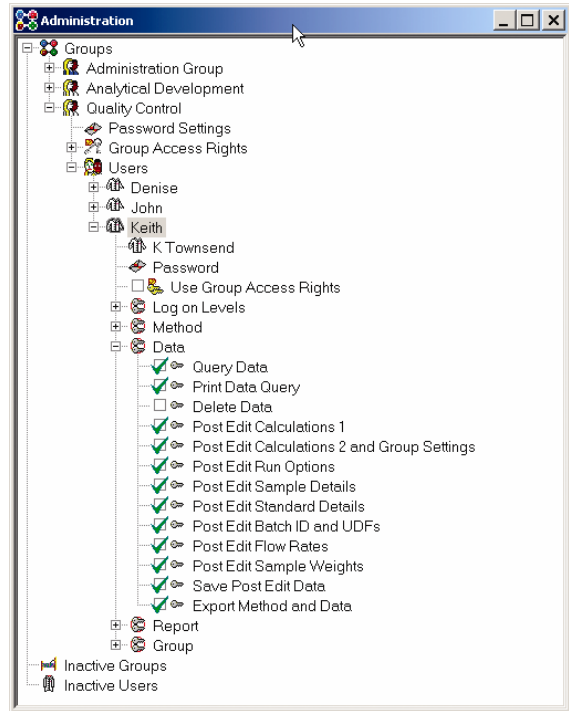


Configurable Centralised Security

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.



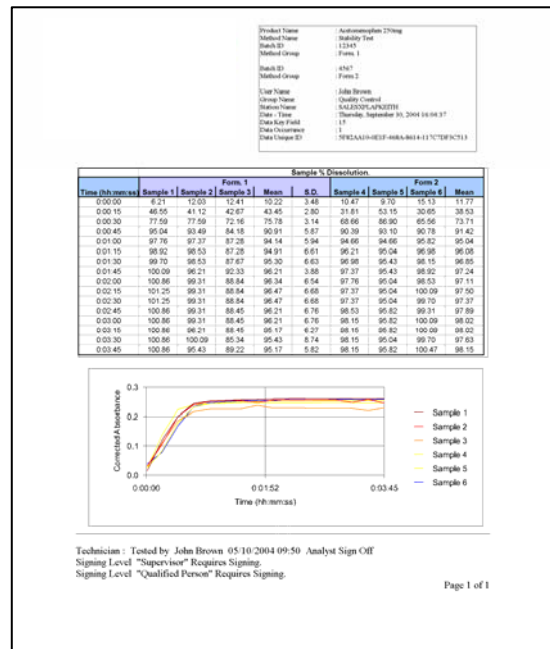
Signing and Reporting Signed Records

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.

Dynamic Report Editor

The WinDiss32 report organiser allows users to produce customised 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.

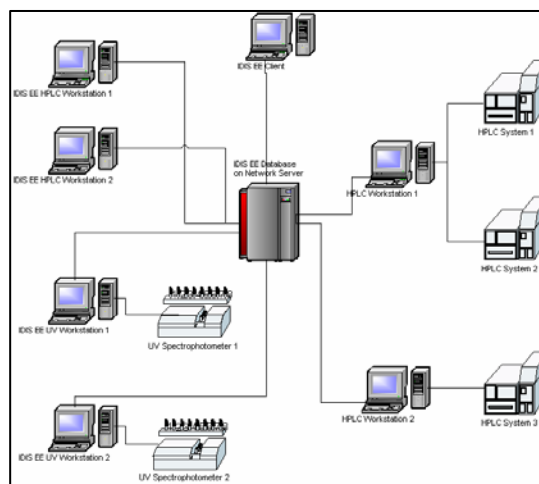
Key Field	User Name	Change Type	Change Comment
164	admin	System Administration	Group "Method Development" has been given the right "Method : Create Method"
165	admin	System Administration	Set the user "John" in group "Method Development" not to use the group rights but use c
166	admin	System Administration	set rights
167	admin	System Administration	Set the user "Patrick" in group "Method Development" not to use the group rights but use
168	admin	System Administration	set rights
169	admin	System Administration	User "Patrick" in group "Method Development" has been given the right: "Method : Delet
170	admin	System Log On Status	User Logged Off
171	admin	System Log On Status	Log On Failed "admin" logging on to level "Device Management" in group "Analytical Dev.
172	John	System Log On Status	User log on successful to level "Device Management" in group "Quality Control"
173	John	System Log On Status	User Logged Off
174	John	System Log On Status	Log On Failed "keith" logging on to level "Application" in group "Quality Control".
175	John	System Log On Status	User log on successful to level "Application" in group "Quality Control"
176	John	Run	Run started for Data ID "BB6F5ACF-C13C-4B79-A5E6-6D45CA7B167E"
177	John	Run	Run completed for Data ID "BB6F5ACF-C13C-4B79-A5E6-6D45CA7B167E"
178	John	Method	Method Re-saved. Changing its ID to "137A1C05-65CB-4ADF-6E77-287F13765EAF" from

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.



Included Bath Driver: IDS 1000

Included Photometer Driver: SA 500 PDA Diode Array Photometer incl. 8-cell changer

Available System Options

- UV light protected vessels
- stainless steel basket inserts to be screwed into the mono-stirrer shafts
- Transdermal testing cylinders and Paddle over Disk assemblies
- Solarisation proof Fibre Probes 1, 2, 5, 10 and 20 mm path length dips

System validation can be done using the USP Reference Standard (RS) Tablets and Standards.

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

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Principle of Operation

The operator describes the operational procedure within the wizard driven software. Then the system will flag when the samples have to be introduced; after this point, the dissolution system works automatically. More or less continuously samples in all active vessels can be analysed and the results are shown online without any delay. As well as the measured absorbance, speed, temperature and pH-values (optional) are recorded. This feature is a important tool in drug formulation and will save a lot of time compared to conventional techniques. The selectable option to run a reference standard solvent, (which is measured in each cycle) or the entry of a theoretical maximum absorbance is available. Running a standard offers some advantages as results that may be influenced by a less than optimum light source, evaporation or temperature influences are corrected by the reference measurement. At the end of a run the operator creates his report and chooses which data that he needs to have printed. As all results remain filed within the system, a batch comparison statistical analysis can be performed at any time.

For further information about dissolution automation ask for the WinDiss32 Dissolution software flyer or for demo 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):

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	1 - 3%