UV-visible spectroscopy solutions for pharmaceutical analysis

Agilent Technologies
Innovating the HP Way

The challenge

Provide UV-visible spectroscopy solutions that satisfy the diverse needs of analysts in routine QA/QC, research, and method development laboratories.

The solution

Systems based on PC-controlled spectrophotometers and a range software – each with features to meet the needs of specific users – plus accessories to enable manual or fully-automated measurements on a wide variety of samples.

What makes Agilent's UV-visible systems

Commitment to ease of use

With the advent of microprocessor and PC control, UV-visible instruments have become more powerful but, at the same time, they have become more difficult to use – especially for simple measurements. Agilent Technologies is committed to reversing this trend by developing intuitive, easy-to-use instruments.

Commitment to GLP

Agilent Technologies believes that manufacturers have the responsibility to help instrument users conform to the requirements of GLP, GMP and 21 CFR part 11.

Commitment to standards

In the modern analytical laboratory compatibility of electronic communication is a major contributor to productivity. Agilent Technologies uses industry-standard hardware and operating systems, and develops software that adheres to industry-standard guidelines and thereby helps with easy data interchange.

Commitment to solutions

Nowadays, simply buying an instrument often does not solve the problem. Agilent Technologies, as a global leader in designing and manufacturing test, measurement and monitoring instruments, as well as semiconductor and optical components, addresses this by offering complete solutions for modern analytical laboratories.

Based on the Agilent 8453 spectrophotometer dedicated solutions are available for
- QA/QC labs
- method development labs
- research labs

In addition special support for 21 CFR part 11 can be added to these solutions.

Commitment to technology

Hewlett-Packard revolutionized the design of UV-visible instruments with diode-array technology in 1979 and today Agilent Technologies continues this commitment to developing new technology as a means to provide you with better, cost-effective solutions.

Agilent 8453 UV-visible spectroscopy system comprising Agilent 8453 spectrophotometer, Agilent ChemStation software running on an HP personal computer, and HP DeskJet printer

different?

The challenge

Help analysts comply with GLP regulations, meet inspector's standards, and increase productivity.

The solution

Systems with built-in tools to help comply with GLP regulations and for verification of the system components.

Good Laboratory Practice

Agilent Technologies and GLP

Agilent Technologies plays a leading role in defining the GLP-related responsibilities of manufacturers and users. And, Agilent Technologies implements features in its products that enable users to comply with GLP regulations quickly, reliably, and productively.

Standards kit

OQ/PV is made even easier using Agilent Technologies standards kit, which meets the needs of both the United States and European Pharmacopoeias. The kit comprises standard solutions in snap-open glass ampules which are inexpensive, easy-to-use and traceable. The standards let you check for photometric accuracy, wavelength accuracy, stray light and resolution.

Validation begins with the manufacturer ...

Agilent Technologies designs and develops products according to documented procedures. Each product is validated before it leaves the factory. The *Declaration of Conformity* document is your assurance that the spectrophotometer meets specifications. The *Declaration of System Validation* describes procedures used in software and system development and is your assurance of software quality.

... and continues on site

All you need for Installation Qualification (IQ) and Operational Qualification/ Performance Verification (OQ/PV) is provided for both the spectrophotometer and system software. Full documentation is included and, where appropriate, procedures are supported by software to save time. IQ and OQ/PV can be performed by the user or are available as services from Agilent Technologies.

Electronic records and signatures

The Agilent ChemStation software in combination with Windows NT and the optional Security Pack can be configured to support the requirements for electronic records and signatures for a closed system as defined in FDA 21 CFR part 11. Tools and products for system installation and operational qualification also complete this solution.

Access Control

Two levels of permissions are defined and managed by the system administrator as user groups within Windows NT. All access control features of Windows NT can be applied such as password aging, uniqueness or account lock.
The Agilent ChemStation login is based on these user groups and checks the permission rights of the users. For example, at the *manager* level, you can develop, modify and save methods, at the *operator* level you only can load and run these methods but cannot save new methods or change existing ones. In the absence of the operator, the running system can be locked for unattended operation.

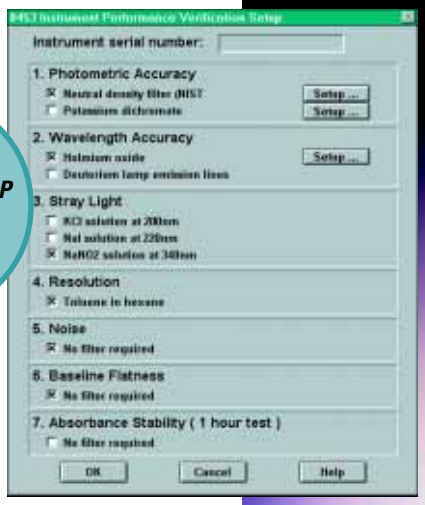
Method integrity

The software saves all method parameters (meta data) in a single, checksum-protected binary file including method history. Existing method files cannot be overwritten.

Data integrity

Agilent Technologies systems measure and save full spectra, even if your current method only uses a single wavelength. Data is automatically annotated with date, time, instrument identifier, operator name, and sample information added by the user. Result files include all information to reprocess the results such as raw data, the complete method as well as logbooks on the run. Even in the case of the operator having deleted a spectrum from the set of spectra, the deleted spectrum and the operators comment are saved with the result file and are available for review.

"Easy compliance to GLP for increased productivity"



Choose the test you need

Data security

The protection of electronic records is one of the most important aspects of data security. The Agilent ChemStation software saves data in checksum-protected binary files. In combination with Windows NT file system permission settings, Agilent ChemStation users can not modify, rename, delete or move any of the data or method files.

Audit trail

The run logbook is automatically generated by the Agilent ChemStation and is always stored with the result file. It contains information such as, who and when the spectra were measured, saved, reprocessed, the calibration modified or the method changed.

Electronic signatures

Users can sign result files electronically with their user ID and password. The purpose of the signature as well as the user name, date and time are stored in the signature logbook together with the individual result file.

Agilent Technologies standards kit and optional OQ/PV hardware kit make OQ/PV easier and save substantial time

The challenge

Provide a powerful and productive system for routine and occasional users that is easy to use and integrates seamlessly in the modern laboratory.

The solution

The Agilent 8453 UV-visible spectroscopy system, combining the PC-controlled Agilent 8453 spectrophotometer with the Microsoft Windows NT-based Agilent ChemStation software.

Solutions for general purpose tasks

Easy to use

The Agilent 8453 UV-visible spectroscopy system may well be the easiest UV-visible system you will ever use. Three steps are all you need to get results.

Graphical user interface

Usability tests performed with actual users in their own labs initiated a completely new approach to user interface design. The Agilent 8453 UV-visible spectroscopy system uses *symbolic graphics* to:

- make the system intuitive, easy to learn, and easy to use,
- provide confirmation of current status at a glance,
- provide visual confirmation of actions, and
- provide fast access to frequently performed activities.

Automation

A single dialog box makes setup for automated analyses easy and quick. You can use automation to guide an operator through a series of manual measurements, or combine it with sampling accessories to provide semi- or fully automated analysis. The automation function controls

- the Agilent sipper system
- Agilent XY autosampler or Gilson autosampler
- the Agilent multicell transport

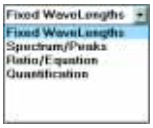
The optional control samples allow you to run an automatic system suitability test before quantitative analyses.

Compatibility

The Agilent ChemStation uses the Microsoft Windows NT environment so you can run other programs, such as word processors and spreadsheets, at the same time, and transfer data using *copy-and-paste*.

Clear and simple reports

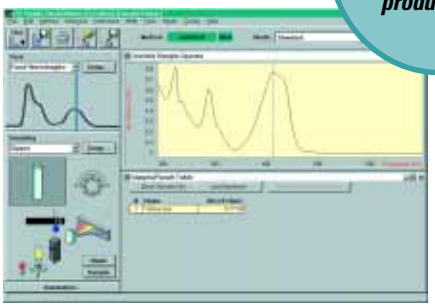
Generating reports could not be easier. Simply click the printer icon in the toolbar and a standard report is printed. When possible this standard report is printed on a single sheet of paper. The report format depends upon the task in use but all reports include essential GLP information such as method and data file name, date, time, operator, overlay of sample spectra and result table.



1. Select the task you want

2. Enter the parameters

3. Do the measurement



Your results are displayed automatically

Print a report

"Easy to learn and easy to use for increased productivity"

The challenge

Provide an easy-to-use UV-visible system that meets the specific needs of the biochemist.

The solution

Add biochemical analysis software to the Agilent 8453 UV-visible spectroscopy system for multicell kinetics, thermal denaturation, and protein/nucleic acid analysis capabilities.

"Key biochemical applications in a single, easy-to-use system"

Solutions for biochemical analysis

Ease of use

The biochemical analysis software builds on the Agilent 8453 UV-visible spectroscopy system. It provides the additional tasks that the biochemist needs and uses the same easy-to-use graphical user interface. Preprogrammed methods for protein and nucleic acid analysis help you get up and running fast.

Proteins and nucleic acids

Standard methods are provided for the qualitative and quantitative analysis of nucleic acids and proteins:

- 260/280 nm ratios (with optional reference at 320 nm) for nucleic acid purity
- Warburg-Christian calculation of concentration of nucleic acid or protein in mixtures
- Biuret, Lowry, Modified Lowry, Bradford, Bicinchoic acid, and Trinitrobenzene sulfonate protein quantification methods

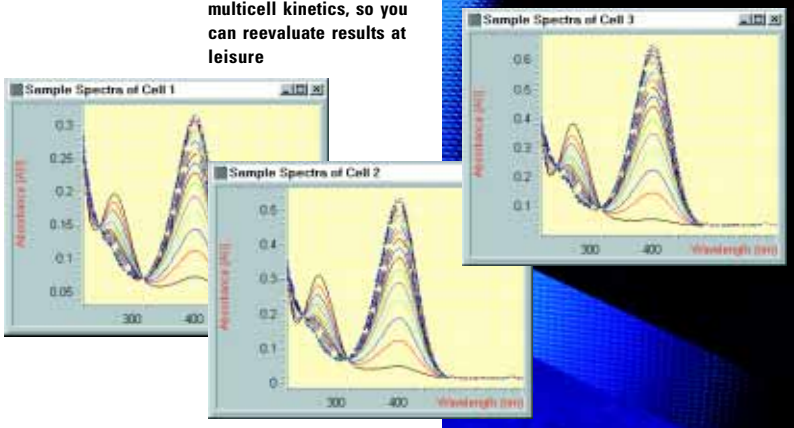
Microsampling

A frequent problem for the biochemist is the small sample volumes available for analysis. With the Agilent 8453 spectrophotometer you can use microcells requiring as little as 15 µl of sample for qualitative and precise quantitative analysis.

Multicell kinetics

For productivity with enzyme kinetic measurements the optional eight-position multicell transport can be used. You can freely configure which positions contain samples and blanks and you can select to subtract the rate of one cell from the others.
You can evaluate kinetic rates at a single wavelength or subtract a reference wavelength. Rate calculation methods include initial rate, zero order, first order, and delta absorbance. For a single cell you can also display and calculate rates at up to six individual wavelengths.

Full spectra are always acquired, even in multicell kinetics, so you can reevaluate results at leisure



The challenge

Provide a powerful and flexible UV-visible spectroscopy system for the method developer with easy transfer of the developed methodologies to routine laboratory systems.

The solution

Add the advanced software to the Agilent ChemStation system to provide special development tools and powerful analysis and automation capabilities.

Solutions for research and method developm

Powerful data analysis

The advanced software provides unprecedented interactive and programmable data analysis capability:

- 17 mathematical functions for processing spectra that you can combine in any sequence
- flexible use of any number of single or multiple wavelengths, or average a range of values
- evaluation using user-entered equations, single-component or multi-component analysis
- up to four different types of data analyses performed on one set of data in parallel
- use confirmation analysis with quantitative methods to check the identity and purity of samples, and to detect if measurements are being made outside the linear range of the analysis

Virtually every aspect of the system can be customized through macro programming.

Method development tools

Four special utilities are provided to assist the user in developing the best parameters for quantitative analysis:

- Evaluate Standards for linearity – performs a single component calibration at each wavelength over a user-specified wavelength. It determines the correlation coefficient and uncertainty at each wavelength.
- Compare Calibrations – puts the results from two independent calibrations side by side on the screen for comparison.
- Optimize Wavelength for selectivity and accuracy – quantifies a user-selected sample at all wavelengths and plots the quantification results against wavelength.
- Test Method for precision – calculates the average and standard deviation of multiple analyses of an identical sample.

Report Customization

A series of predefined reports are available in the software. However, to fulfill specific needs, the user can define their own customized reports based on the predefined reports or user defined template.

Multicomponent analysis

Multicomponent UV-visible analysis can provide a real alternative to time-consuming separations. Fast electronic scanning, spectral curve fitting of standards to unknowns, excellent wavelength reproducibility, and maximum-likelihood statistics make sure that results are superior to those obtained with conventional mechanical-scanning spectrophotometers. Calibration is simple and fast using pure standards or mixtures of standards.
Statistics for the fit of the standards to the sample spectra give you confidence in your results.

Advanced automation

With the advanced automation capability you can perform fully automatically complex measurement, data evaluation, and report generation sequences using single or multiple methods for different types of samples. It can also be used to guide an operator through a complex sequence of manual measurement operations. Complex methods or

Multi-component analysis with diagnostic tools that show the quality of the results

e n t

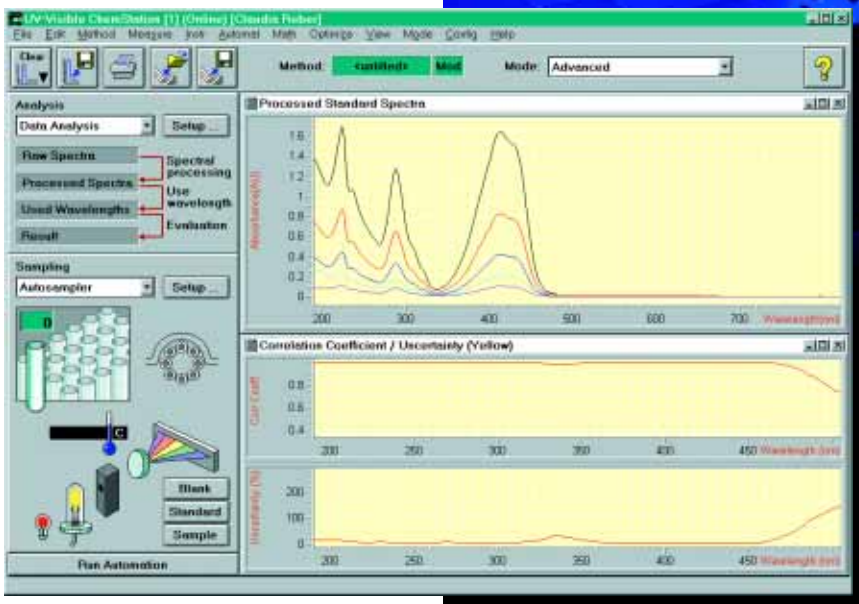
automation processes that you develop on the advanced system can be transferred to and executed on the general purpose system.

Electronic records and signatures

The advanced mode can be combined with the security pack to support 21 CFR part 11.

"The power and flexibility to develop the optimum method and solve the toughest problems"

The Optimize Standards function shows the wavelengths that give the best calibration



The challenge

Provide an easy-to-use, flexible, and productive dissolution testing system for formulation development and QA/QC.

The solution

Add the dissolution testing software to the Agilent ChemStation system to provide the specific data evaluation and sampling system control.

Solutions for dissolution testing

Ease of use

The dissolution testing software builds on the Agilent ChemStation platform. It provides the additional tasks that are required for data evaluation and reporting and uses the same easy-to-use pictorial user interface.
All parameters necessary to perform a dissolution test are stored in a single method file. Methods include procedures that guide the operator through the specified tasks.

Real-time display

During the dissolution test you get full overview of the system and bath status and the progress of the dissolution process. The graphical profile display shows in real-time the progress in all vessels. A numeric display shows you the actual values for each vessel at the measurement time as well as the average and statistics. A spectral window always shows all spectra of the last cycle.

Integration of third-party equipment

The open architecture of the third-party interface allows integration of baths through Dynamic Data Exchange (DDE). Major bath manufacturers provide the necessary drivers to allow control of the baths through Agilent ChemStation. Data acquired from the baths are also included in the common result file and final report. For fully automated dissolution testing the system can be combined with automation systems such as the MultiDose dissolution workstation from Zymark Corporation.

Calculations and reports

Dissolution results are calculated in real-time and reported based on different options. The software can compensate for volume changes caused, for example, by pH change, sampling or evaporation. This volume change function can be used to allow processing of dissolution data from the flow-through and "Biodiss" apparatuses (USP 3, 4).
Reports are based on a variety of predefined templates and include all GLP relevant information such as operator, date, calibration, and dissolution bath results. To adapt the report to your specific needs the report layouter can be used to create custom report formats.

Good Laboratory Practice

The dissolution testing software features specific tools for dissolution testing to help to comply with GLP regulations such as user defined pre- and post- dissolution sequences:

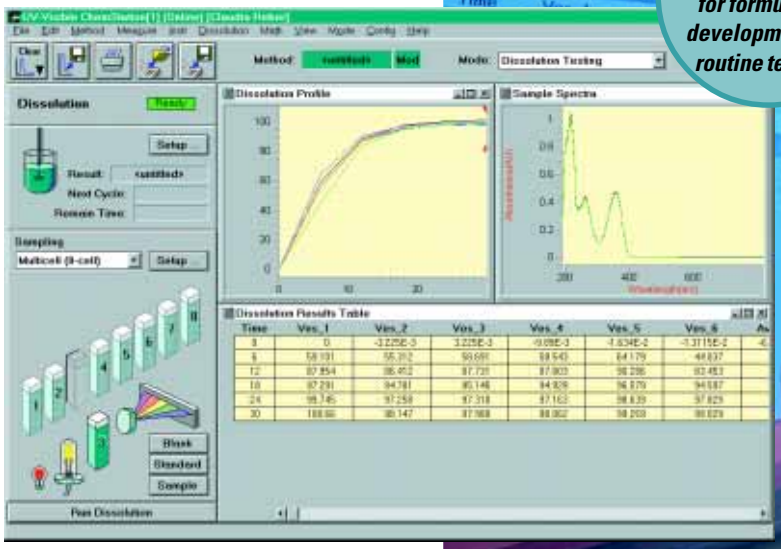
- users can load only those methods for which they have permission
- flow rate check of pump
- transfer of bath parameters to the bath
- wash cycle to clean the tubing
- remeasure standard
- measure control for a system suitability test
- medium test

Standards and samples are measured and stored in the result file as full spectra for positive sample identification and proof of purity. In the rare case of something going wrong, the availability of all sample spectra is also very useful and can shorten an investigation dramatically.
All method parameters (meta data) as well as different logbooks are also stored in the result file for complete documentation and reprocessing capabilities from a single source.
In addition, all features are available which are built in the verification and diagnostic software.

Electronic records and signatures

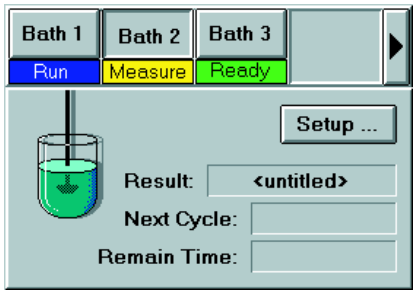
The dissolution testing mode can be combined with the security pack to support 21 CFR part 11.

The run-time display shows profiles, actual values and the last spectra as well as the status of instrument at a glance



"The most flexible and adaptable system for formulation development and routine testing"

The user-defined sequence guides the operator through the tasks done before a dissolution run



High-throughput QA/QC dissolution testing on up to four baths simultaneously

The challenge

Provide an easy-to-use, flexible, and productive dissolution testing system for formulation development and QA/QC.

The solution

The Agilent 8453 UV-visible dissolution testing system controls the whole range of sampling systems, from manual to fully automated.

Sampling systems

Offline dissolution testing

In offline dissolution testing the samples are collected independently from the analytical system. These samples are measured by the Agilent 8453 UV-visible dissolution testing system using standard cells or, for more convenience, with a sipper. In both cases the operator is prompted for the specific sample. For unattended operation an autosampler can be used. In all cases the sampling for blank, sample and control, is user definable.

Online dissolution testing

In online dissolution testing the sampling is done automatically direct from the dissolution bath under control of the dissolution testing system. Choose a multicell or a valve-based sampling system. For high-throughput QA/QC dissolution testing up to four baths can be sampled from one Agilent 8453 dissolution testing system.

Multicell-based sampling system

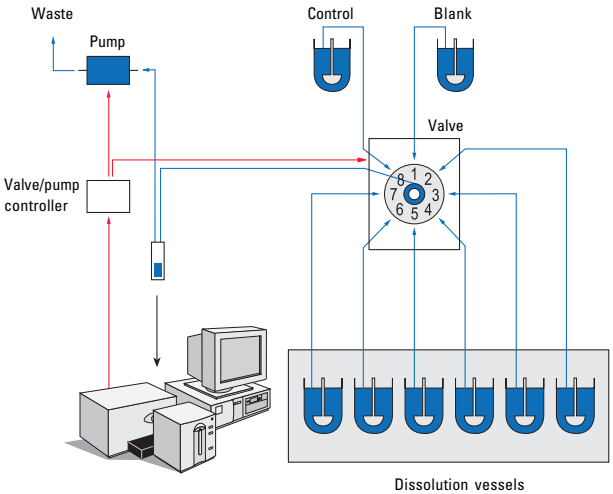
The multicell system is the most commonly used sampling system with single bath testing. It uses a multicell transport with eight flow cells, one for the blank, up to six for the individual vessels and one for a control, and a multi-channel pump to sample all vessels simultaneously. A minimum cycle time of two minutes is possible. The dissolution medium is recycled so that there is no change in medium volume during the test. This system is the most versatile one and ideally suited for low volume QA testing as well as formulation development.

Valve-based sampling system

The valve-based system is the most cost-effective solution. It uses an eight-port valve to switch between blank, control and the six dissolution vessels, and has a single channel to transfer the sample. Because the sampling is sequential, the minimum cycle time is five minutes. At each sampling cycle a small volume (about 4 ml) of dissolution medium is lost but the software can correct for this loss during calculation of the results.

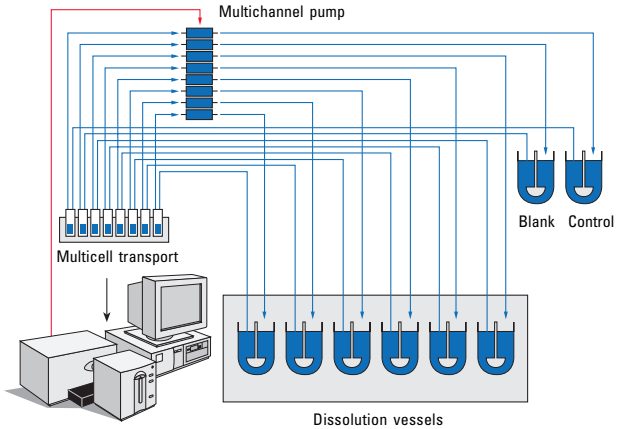
Multi-bath sampling for increased productivity

When you have large numbers of samples to analyze the Agilent 8453 dissolution testing system in combination with the valve-based, multi-bath sampling system gives you the highest productivity. The system can measure a blank, six vessels and a control in up to four baths all within five minutes. On each of the baths an individual method can be used. The methods and features are identical as with the single-bath, valve-based system.

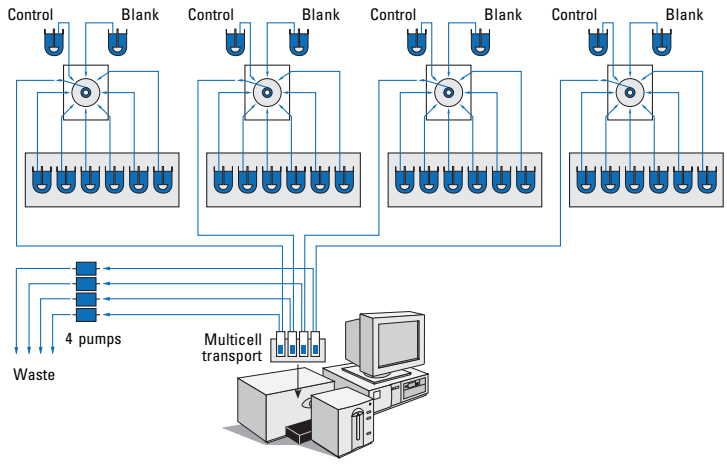


Single-bath valve-sampling system

"Scaleable sampling from manual offline through fully automated online (with up to four baths)"



Single-bath multicell-based sampling system



Multi-bath dissolution sampling system

Sipper operation is easy with built-in measurement buttons

Side door for easy lamp change

Agilent 8453 UV-visible spectrophotometer

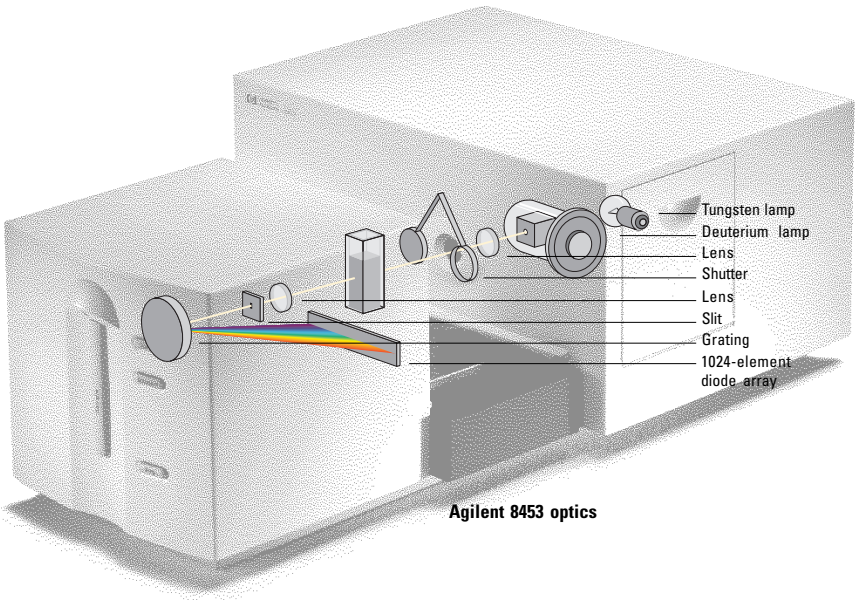
The Agilent 8453 UV-visible spectrophotometer offers the latest in diode-array technology:

- compliance with all requirements of the European Pharmacopoeia (EP) and United States Pharmacopeia (USP)
- small footprint to save bench space
- prealigned deuterium and tungsten lamp light sources for trouble-free maintenance
- built-in buttons to measure sample, standard, and blank for convenient measurements even when wearing gloves
- thermally stable ceramic spectrograph for a wide operating temperature range
- communication through GPIB or LAN for dedicated or networked PC control
- firmware upgrade from PC for easy participation in future developments
- built-in GPIO interface for control of accessories

Good Laboratory Practice

The Agilent 8453 supports compliance with GLP regulations:

- serial and firmware revision number held in firmware
- own clock for time and date stamps of the spectra
- extensive self-test procedures that check the electronics and key optical characteristics to ensure consistent performance between validation
- built-in electronic logbooks which contain the results of self tests, notes on instrument
- maintenance, events and errors



Agilent 8453 optics

Optical performance

The Agilent 8453 offers the advantages of a diode array plus significant improvements in optical performance:

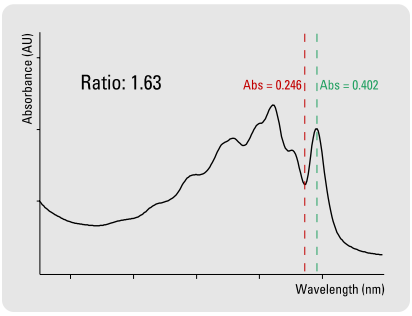
- 190–1100-nm wavelength range
- 1-nm slit width
- <0.03 % stray light

The diode-array advantages

Backed by over two decades of experience in the development and manufacture of diode-array spectrophotometers, the Agilent 8453 gives you clear advantages.

- Fast spectral scanning for complete spectral information useful for:
  - Proof of identity and pureness of the sample
  - Additional information for "out of specification test result" investigation in a regulated environment
  - Re-evaluation with different method
  - Multi-wavelength applications such as user-defined equations
- Open sample area for convenient sample handling.
- High throughput optics guarantees excellent signal-to-noise for high sensitivity.
- Virtually absolute wavelength resettability allows selection of optimum wavelength and use of electronic standards.
- Exceptional ruggedness and reliability.

Open sample area means large accessories are easy to use–here the Peltier cell holder



Spectrum of a 0.02 % v/v solution of toluene in hexane

Specifications – Agilent 8453 UV-Visible spectrophotometer

Optical performance

Wavelength range	190–1100 nm	
Slit width	1 nm	
EP resolution test	>1.6	toluene in hexane, ratio abs. at 269 nm/266 nm
Stray light	<0.03 % <0.05 % <1 %	at 340 nm ($NaNO_2$, ASTM) at 220 nm (NaI, ASTM) at 200 nm (KCl, EP)
Wavelength accuracy	<±0.5 nm <±0.2 nm	0.5-second scan (NIST 2034) at 486.0 and 656.1 nm
Wavelength reproducibility	<±0.02 nm	ten consecutive scans (NIST 2034)
Photometric accuracy	<±0.005 A <±0.01 A	at 440.0, 465.0, 546.1, 590.0, and 635.0 nm, 1 A (NIST 930e) at 235, 257, 313, 350 nm, at 1 A (potassium dichromate, EP method)
Photometric noise	<0.0002 A	sixty 0.5-second scans at 0 A, 500 nm, rms
Photometric stability	<0.001 A/h	at 0 A, 340 nm, after 1-hour warm up, measured over 1 hour, every 5 seconds, constant ambient temp.
Baseline flatness	<0.001 A	0.5-second blank, 0.5-second scan, rms
Typical scan time	1.5 second	full range
Shortest scan time	0.1 second	full range
Time until next scan	0.1 second	full range, 0.1-second scan, up to 150 consecutive scans

Physical dimensions

Height × width × depth	185 × 344 × 560 mm (7.3 × 13.5 × 22.0 inches)
Weight	16.5 kg (36.3 lb)

Power requirements

Line voltage	90–264 V AC
Line frequency	47–63 Hz
Power consumption	70 VA typical

Environmental conditions

Operating temperature	0–50 °C (32–122 °F)
Non-operating temperature	-40–70 °C (-4–158 °F)
Humidity	<95 %, at 25–40 °C (77–104 °F)

The ceramic chassis used in the Agilent 8453 spectrophotometer is manufactured under license from Carl Zeiss.

Accessories

Cell holders

Agilent Technologies offers a range of single cell holders, providing you with the ability to analyze a wide variety of samples. Unless otherwise stated the holders accept cells with path lengths up to 10 mm.

Standard cell holder: Ensures quick and precise cell positioning for each measurement. Supplied standard with all Agilent Technologies spectrophotometers.

Thermostattable cell holder: When connected to a circulating-water bath, ensures constant sample temperature for temperature-sensitive analyses. An optional accessory provides water-driven stirring with magnetic stirring bar for 10-mm cells.

Long-path cell holder: Holds rectangular and cylindrical cells with path length up to 100 mm.

Multicell transport

The multicell transport provides a significant increase in productivity when you need to do simple, repetitive measurements on a small number of samples, or when you want to follow changes in several samples (for example, enzyme kinetic studies). The multicell transport features:

- full control through software,
- eight cell positions (for example, one blank and seven samples),
- random access to all positions,
- water thermostattable using external water bath, 5–90 °C temperature range and ±0.3 degrees temperature difference between any two cells at 37 °C,
- <1 second to move between adjacent cells, and
- ±0.1 mm position repeatability.

Peltier thermostatted cell holder

Use the Peltier controller and cell holder when you require precise or variable temperature control:

- built-in magnetic stirrer,
- heat exchanger for sample pre-heating when using a sipper system,
- fully controlled through software and GPIB interface,
- external sensor for precise sample temperature (optional),
- typical range of 10–100 °C (-10 to +80 degrees relative to ambient) without need for water cooling,
- accuracy of ±0.2 degrees at 20–40 °C, ±0.3 degrees at 0–20 °C and 40–60 °C, ±0.5 degrees at 60–100 °C,
- reproducibility of ±0.1 degrees at 0–60 °C, ±0.2 degrees at >60 °C, and
- stirrer speed of 40–1000 rpm.

Sipper system

For repetitive measurement of liquid samples a sipper system improves productivity and eliminates errors caused by manual cell handling. The Agilent sipper system comprises a peristaltic pump and a quartz flow cell:

- full control through software,
- variable pump, delay, and return time,
- flow cell with 10-mm path length, 3-mm diameter, and 80-µl volume,
- constant-speed peristaltic pump with Tygon pump tubing,
- minimum sample volume of approximately 1 ml, and
- typical sampling time of 20 seconds (with <1% cross-contamination).

Autosampler

Combine an XY autosampler with a sipper system and you can measure large numbers of samples fully automatically in unattended mode. The XY autosampler features:

- full control through software,
- capacity of up to 240 samples,
- wash station for optional rinsing between samples,
- 10–13-mm diameter sample tubes with maximum height of 100 mm,
- typical transit time (adjacent samples) of approximately 6 seconds (including raising and lowering probe),
- typical time per sample of 25 seconds (including sipper operation time), and
- minimum sample volume of 2 ml.

Cells

Agilent Technologies offers a range of quartz cells for standard and flow-through operation including:

- Regular rectangular cells with path lengths of 1, 2, and 10 mm.
- Cylindrical cell with 100-mm path length.
- Stoppered cells to protect your sample from air and ideal for use with the external sensor of the Peltier temperature controller.
- Flow cells with rectangular, oval or circular apertures with screw fittings and path lengths of 1, 2, 5 and 10 mm.
- Semi-micro and micro cells with path lengths of 2 and 10 mm for minimum sample volumes of 15 and 60 µl respectively.

For more details see the *Agilent Technologies Columns and Supplies Catalog.*

Third-party accessories

A wide range of accessories, designed for or compatible with Agilent Technologies spectrophotometers are available:

- **Gilson** autosamplers that are controlled directly from the Agilent Technologies ChemStation software,
- **Labsphere** diffuse reflectance accessories,
- **Applied Photophysics** stopped-flow accessory for fast kinetics,
- **Hi-Tech** stopped-flow accessory for fast kinetics,
- **Distek** dissolution baths, and
- **Zymark** MultiDose dissolution workstation.

Ask your Agilent Technologies representative for more details.

Agilent Technologies support

Agilent Technologies has support centers in 85 countries supplying a wide range of support products that can be tailored to your needs.

For example, the Agilent Technologies network of Analytical Response Centers provides direct access to support professionals who help you resolve operational difficulties, and offer assistance and advice on running Agilent Technologies chemical analysis software. They also help you to solve analytical problems, to keep your equipment up to date, and to maintain GLP standards.

All of us at Agilent Technologies are here to help you meet your chemical analysis goals, not just now but also long into the future.

Security software module for compliance to 21 CFR part 11	**Security Pack**		
Software modules	**Advanced**	**Dissolution** Dissolution testing Multibath dissolution testing Combined report	**Biochemical Analysis** Kinetics Thermal denaturation
8453 spectroscopy system with standard software	**General Purpose** Verification and diagnostics		

Agilent's UV-visible spectroscopy solutions for

Selection of software modules

Adapt the 8453 spectroscopy system to your needs by adding different software modules to the general-purpose software. One or more modules can be added to at the same time to support different applications.

If you work in a regulated environment, add the security pack software for help with compliance to 21 CFR part 11. Please note that for full support of 21 CFR part 11, the advanced and/or the dissolution testing software is required. An overview on the different features is given in table 1.

Table 1
Compatibility of Security Pack software

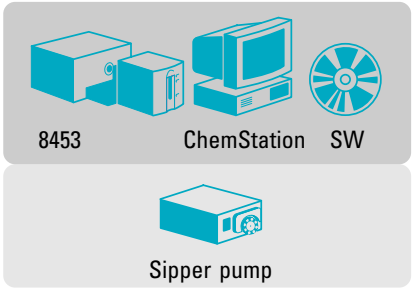
	Software mode			
Feature	**Standard mode**	**Advanced mode**	**Dissolution mode**	**Kinetic mode**
				not supported
Raw data protection	YES	YES	YES	–
Storage of raw and meta data	NO	YES	YES	–
Mandatory log-on	YES	YES	YES	–
Versioning on the ChemStation side	NO	YES	YES	–
Electronically signing off	NO	YES	YES	–
Application lock *	YES	YES	YES	–
Audit-trail method	YES	YES	YES	–
Audit-trail raw/meta data	NO	YES	YES	–
Archiving built-in **	NO	NO	NO	–
Password policy part 11	YES	YES	YES	–
Data recovery tools **	NO	NO	NO	–

* Not mandatory for part 11 compliance but important in production environment.
** Not mandatory for part 11 compliance, but highly recommended for the data security and long-term data storage. These tasks have to be done by the IT department.

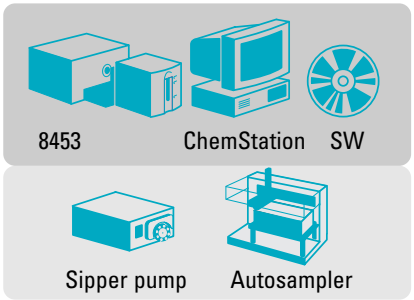
Increasing productivity

The ChemStation software allows control of different sampling systems to increase throughput. A common feature of the general purpose, advanced and dissolution software is that the predefined methods work with different sampling systems – without changing parameters. Therefore, a method developed for manual sampling can easily be used with a sipper or autosampler, depending on the actual demand.

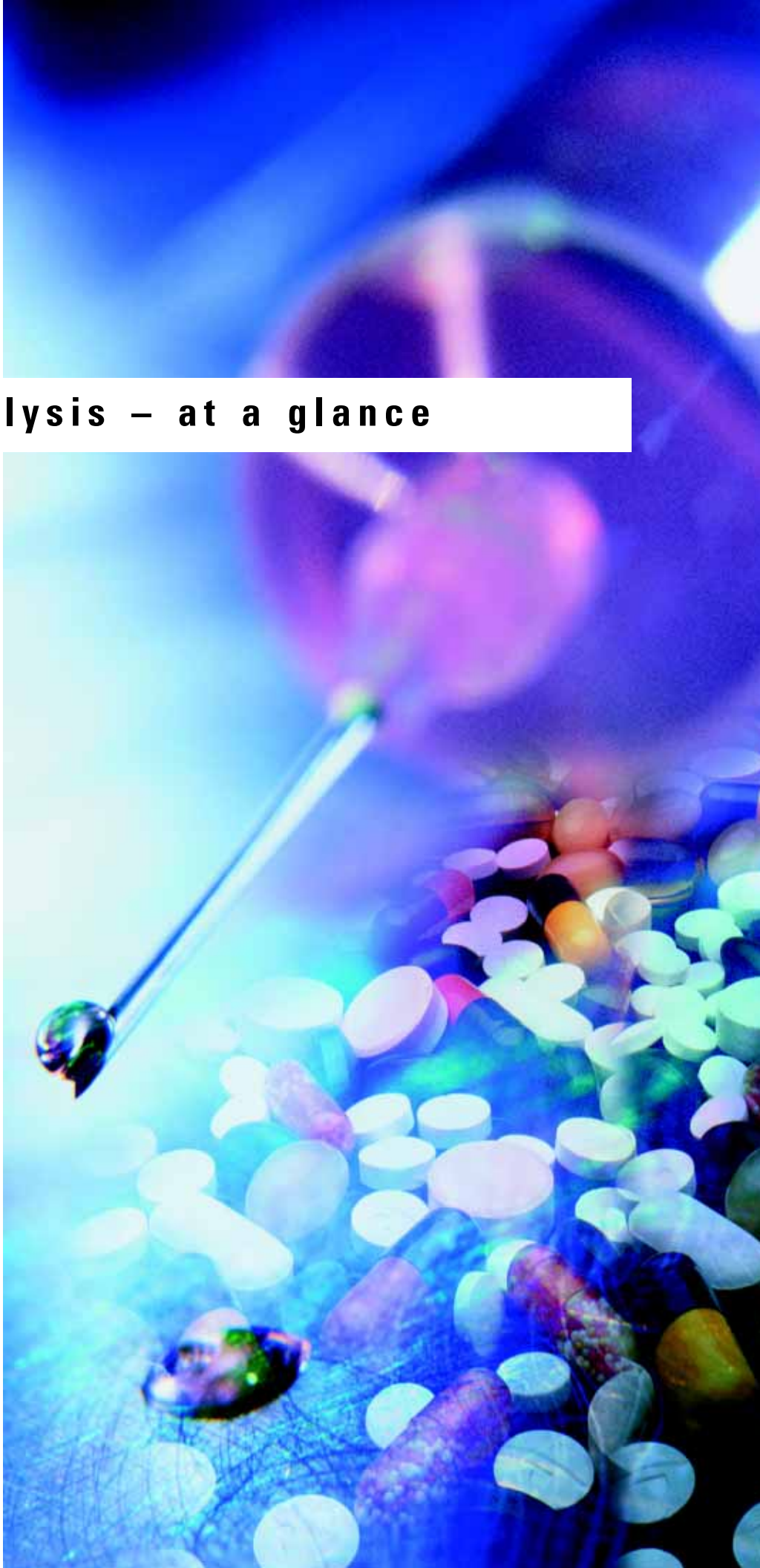
For convenient operation and medium sample throughput the sipper system is recommended.
A sipper system consists of:



For unattended operation and high sample throughput, the autosampler system is recommended. It consists of:



pharmaceutical analysis – at a glance



Selecting the dissolution sampling system

For offline dissolution testing, you can add a sipper or autosampler for increased productivity.

For online dissolution testing, two kinds of sampling systems are available, parallel sampling using a multicell transport or sequential sampling using a valve.

Select the valve system if:
- upgrade to a multibath system is planned
- only one flow cell should be used
- staggered tablet drop is not a problem
- budgets are tight

Select the multicell-based system, if
- a closed loop system is required
- minimum cycle times must be achieved
- parallel sampling is required for automated tablet drop or basket methods

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