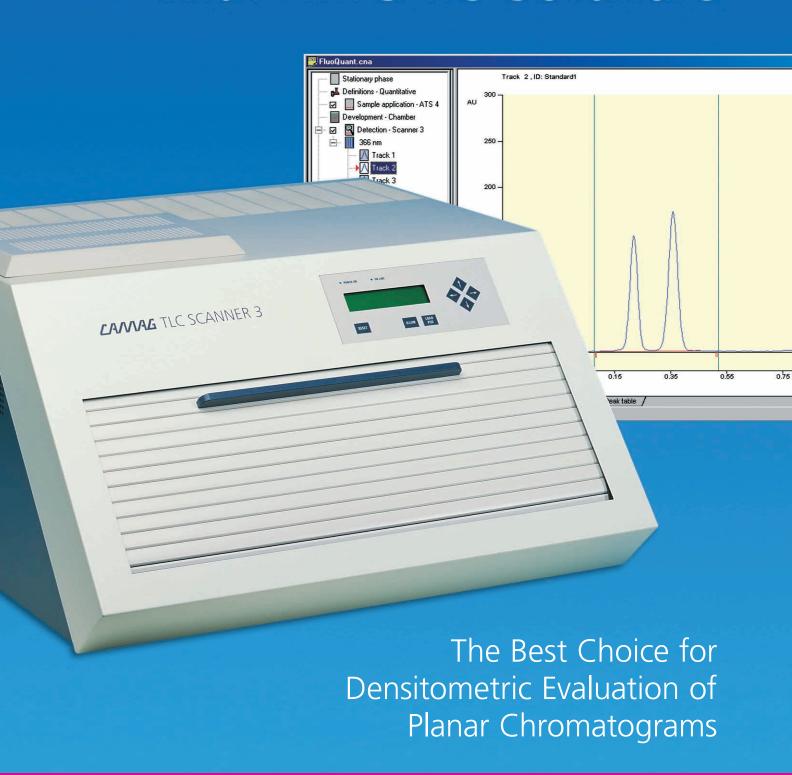
ZA/VAG

TLC Scanner 3 with winCATS Software



TLC Scanner 3 in Planar Chromatography





Clinical applications

- Lipids
- Metabolism studies
- Drug screening
- Doping control
- etc.



Food analysis/animal feed

- Quality control
- Additives, e.g. vitamins
- Pesticides
- Stability testing
- etc.



Pharmaceutical industry

- Quality control
- Content Uniformity Test (CUT)
- Identity/purity check
- Stability testing
- etc.



Industrial applications

- Process development and optimization
- In-process control
- Cleaning validation
- etc.



Forensic

- Detection of document falsifications
- Poisoning investigations
- Dye stuff analysis
- etc.



Environmental analysis

- Water
- Soil
- Residue analysis
- etc..

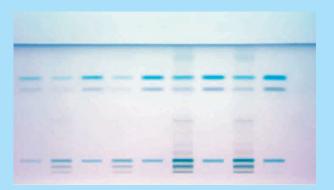
CAMAG TLC Scanner 3



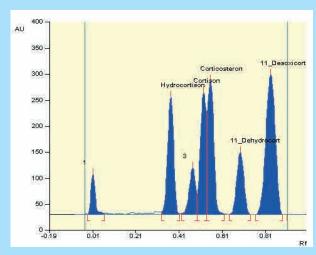
The **CAMAG TLC Scanner 3** is used for the densitometric evaluation of objects from the fields of planar chromatography and electrophoresis.

- The scanner is designed to handle objects up to 200 × 200 mm.
- As required, scanning can be performed in reflectance or transmission (optional) mode, by absorbance or by fluorescence.
- The scanner features three light sources, a deuterium lamp, a halogen-tungsten lamp and a high-pressure mercury lamp.
- The scanning speed is selectable between 1 and 100 mm/s.
- The spectral range is 190 to 800 nm.
- The entire spectral range can be used for spectra recording; if the emission range of one lamp is exceeded the scanner automatically switches to the next lamp.
- Spectra recording is performed with up to 100 nm/s at an oversampling rate of 40/nm.
- The scanner is connected via RS 232 interface to a computer which controls all actions, processes data and generates the report.

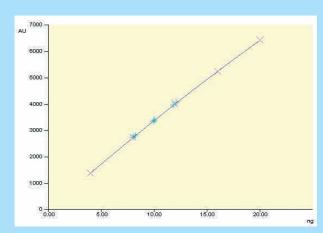
The object, here a 20×10 cm HPTLC plate, is fixed onto the scanning table and then simply inserted. If the user positions the stage manually, the coordinates can be automatically used by the program.



(9) Planar Chromatogram



(10) Analog curve



(11) Calibration function

User-friendly operation

All functions of the scanner are controlled by the computer, only the object to be scanned must be inserted manually. If the operator so desires, he can switch on the internal illumination and position the stage manually.

The electronic amplification is set automatically. In fluorescence mode, this is performed with a "quick scan", which measures the complete plate, e.g. 18 tracks in 20 seconds, and determines the optimized settings from the result. The 16 bit A/D converter ensures optimum resolution of the signal. This is particularly useful for the measurement of both low absorbance and weak fluorescence signals.

Scanner operation with winCATS is convenient and easy to learn.



(12) The object, here a 20 × 10 cm HPTLC plate, is positioned on the scanning table and simply inserted. The coordinates are displayed during manual positioning of the stage and can be entered into the program by mouse click.

The Optical System

 Any of the three light sources, high-pressure mercury lamp, deuterium lamp, or halogen-tungsten lamp can be positioned in the light path by a motor drive.

- Entrance lens system

 Monochromator entry slit

 Monochromator grating

 Disk with slit apertures

 Light path schematically

 The photo aligned at mission mobject is used to be a support of the measuring photomultiplier to
- All components of the optical system, lamps, monochromator, scanning stage, and photomultiplier are mounted on one sturdy metal support.
 This ensures high precision of the detector signal.

the actual emission intensity of the lamp at the

aging and short-time fluctuations. It also reduces

current wavelength. It compensates for lamp

the warm-up time required to reach lamp

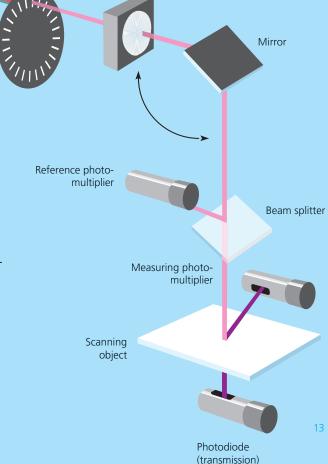
- For scanning at wavelengths below 200 nm it is advisable to flush the monochromator with nitrogen. The scanner is prepared for this.
- A monochromator bandwidth of 5 nm or 20 nm can be selected. 5 nm bandwidth is used for spectra recording, multi-wavelength scanning, and always when spectral selectivity is required.
 20 nm bandwidth offers higher light intensity and enables several fractions with differing absorption maxima to be measured in one scan.

- The lens system with 190–800 nm transmission range features automatic positioning for micro and macro slit sizes. This ensures that the light energy available with small slits in the micro position is almost the same as that for the corresponding slit in the macro position, which is four times larger.
- The light beam strikes the object at right angle.
 The photomultiplier for reflectance scanning is aligned at an angle of 30°. For scanning in transmission mode a photodiode mounted below the object is used as detector.

Lens system, can

be positioned for

micro and macro slit



Technical Data

Light sources

Deuterium lamp, usable continuum 190–400 nm Halogen tungsten lamp, usable continuum 350–800 nm

High-pressure mercury lamp, line spectrum 254–578 nm

Lamp power supply

The lamp, which is positioned in the light path, is automatically ignited. The tungsten lamp can remain lit with either of the other two. All lamps are current stabilized

Pilot lamp and compartment illumination

The slit is automatically illuminated with visible light when the compartment illumination is switched on. The scanning compartment is illuminated with a 4 watt fluorescent tube UV 254 nm which the user can replace by a UV 366 nm or a white light tube.

Optical system

Apochromatic suprasil-fluorite lens system, transmission range 190–800 nm, astigmatic entry lens for optimal slit illumination; automatic switching between micro and macro position for optimal light intensity

Monochromator

Concave holographic grating, 1200 lines/mm, bandwidth selectable 5/20 nm, wavelength range 190–800 nm; monochromator driven by stepper motor, reproducibility of wavelength setting better than 0.2 nm, accuracy better than 1 nm; connector for flushing with nitrogen. Maximum speed of spectra recording 100 nm/s, positioning at 200 nm/s. Motor-driven filter wheel with two automatically selected filters for the elimination of second order wavelengths; 400 nm cut-off filter for fluorescence measurements; three positions for user selected filters

Scanning slit

Revolving disk with 20 fixed apertures; length of slit images selectable between 0.5 and 12 mm, width between 0.025 and 1.2 mm in 38 combinations

Detector

Reflectance mode: two matched broad band photomultipliers, multialkali type, spectral sensitivity 185 – 850 nm

For transmission mode (optional) silicon photovoltaic detector (diode); spectral sensitivity 185 – 1150 nm; linear range 0–3.0 OD

Stage drive

Independent in both directions by stepper motors, micro step driven for smooth movement; reproducibility of positioning better than 50 μ m in Y-direction, better than 100 μ m in X-direction, maximum scanning speed 100 mm/s, positioning at 150 mm/s

Mains voltage

Selectable 100 V, 120 V, 220 V, 240 V; 50/60 Hz, 130 VA

A/D converter

16 bit, 2-channel A/D converter, 100 ms per double conversion

Connections/interfaces

Serial interface RS232 for communication to a PC, Equilink for connection to winCATS Planar Chromatography Manager

Dimensions

620 × 620 × 345 mm, net weight 38 kg



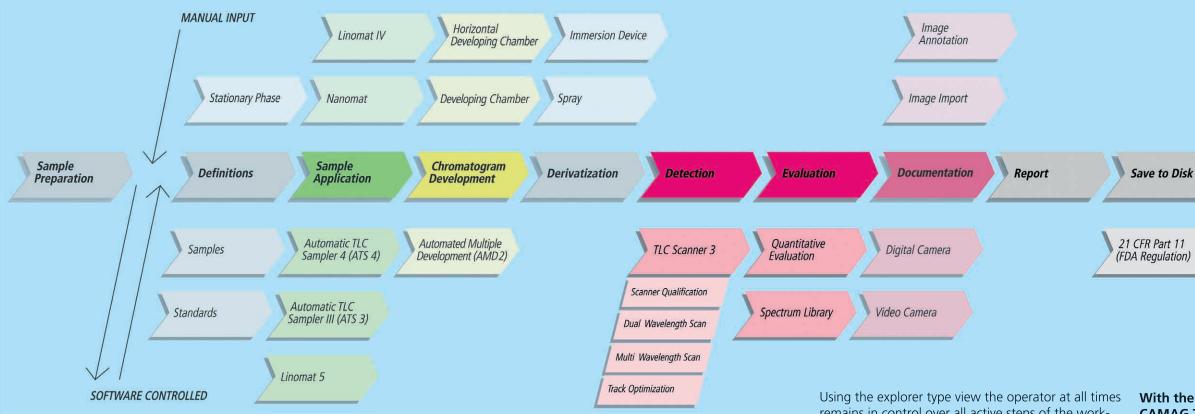
(14) Extension kit for transmission measurements: transparent stage module, plug-in detector assembly and accessories.



(15) Preventive maintenance and troubleshooting is easy: the printed boards are accessible from the side.

winCATS Planar Chromatography Manager

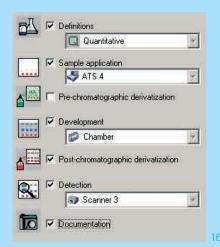




CAMAG has been developing software for densitometric evaluation of planar chromatograms and electrophoresis objects since 1980.

winCATS is the result of a unique integrated software concept covering all steps of planar chromatography. The user can combine the individual modules to create a complete solution that meets all requirements with respect to instrument control, data acquisition, evaluation and documentation.

The modular design of **winCATS** allows selecting or disabling the individual steps of planar chromatography according to the task at hand.



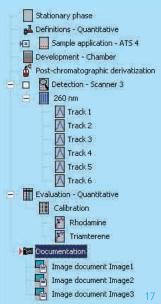
8

The program offers a unique combination of features:

- winCATS combines high performance with easy
- winCATS offers a two-stage on-screen HELP system, a brief info line and a detailed explanatory
- winCATS features a structured data management and high data safety with easy access to network and project directories.
- winCATS stores the complete set of parameters used – together with all data – from scanning raw data to documentation – in one single file, and prints everything if desired.
- winCATS complies with the rules of GMP/GLP and 21 CFR part 11.

remains in control over all active steps of the workflow. These are:

- Selection of plate material and its pretreatment
- Definition of samples, standards, and the calibration method if applicable
- Sample application
- Chromatogram development
- Derivatization (pre and/or post chromatographic)
- Detection
- Spectra recording
- Quantitative evaluation
- Documentation



With the winCATS standard program the CAMAG TLC Scanner 3 is a most versatile instrument featuring a multitude of functions:

- The maximum scanning speed is 100 mm/s; up to 36 tracks with up to 100 substances can be evaluated.
- Integration is performed with either automatic baseline correction and peak detection or user
- Assignment of substance names by means of the graphic user interface is straight foreward.
- The spectra of all detected peaks can be measured automatically.
- Color graphs of all data, ranging from 2D analog curves with substance names to complex 3D displays can be printed and exported.

winCATS program options for TLC Scanner 3

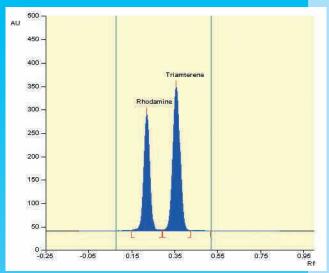
- Quantitative evaluation: page 12
- Sub-component evaluation: page 13
- Spectrum library: page 15
- Track optimization: page 16
- Dual wavelength scan: page 16
- Multi wavelength scan: page 17
- Scanner qualification: page 18
- 21 CFR Part 11 "compliance ready": page 19

For further information and current state of implementation visit www.camag.com

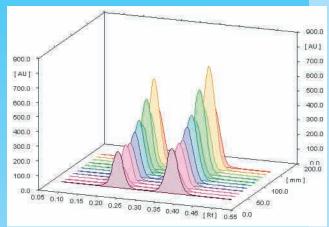
Data Acquisition – TLC Scanner 3



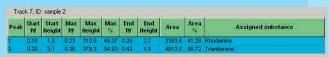
(18) Input screen for scan parameters.



(19) Integrated peaks with substance names; at this stage baseline and integration limits can be manually changed by mouse action.



(20) 3D diagram of all analog curves of the current plate.



(21) Table of integration results for the selected track.

For routine analysis winCATS starts off with a method file containing all relevant data for the current task such as instruments, parameters, etc. This method can be validated for GxP work. From this method an analysis file is generated and parameters unique to the actual analysis, i.e. sample designations, amounts, etc. are adapted.

When, after sample application and chromatogram development the procedure has reached the data acquisition with TLC Scanner 3, the plate is positioned on the stage and scanning is started.

Slit dimensions, scanning speed, light source, wavelength, etc. have already been defined within the method.

The TLC Scanner 3 scans the plate and transfers raw data back to winCATS where baseline correction and peak recognition is performed automatically in the background.

The display can be swiveled and tilted, and additional information can be displayed by clicking the right mouse key on an analog curve.

Analog curves can be displayed either individually or in a 3D diagram. Both can be printed in color together with the analysis report.

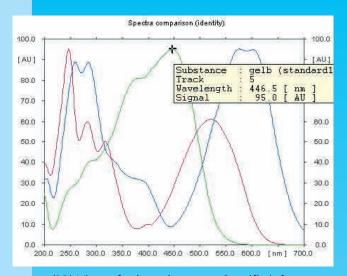
Recording of spectra

winCATS can automatically record spectra as soon as all peak positions are known. Spectra can be displayed individually or overlaid in one diagram.

Spectra can be measured from 190 to 800 nm. If the emission range of the deuterium lamp is exceeded the scanner automatically switches to the halogen-tungsten lamp. Both lamps remain ignited.

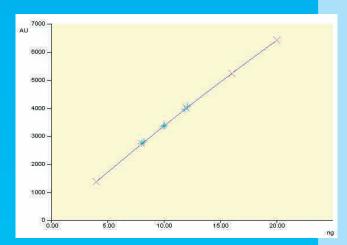
	Track	Rf	Assigned Substance	Max Signal	Display
6	2	0.38	Hydrocortison	297 AU @ 250 nm	V
7		0.53	Cortison	335 AU @ 247 nm	✓
8	2 2 2 2	0.56	Corticosteron	343 AU @ 249 nm	✓
9	2	0.70	11_Dehydrocort	176 AU @ 246 nm	✓
10	2	0.84	11_Desoxicort	350 AU @ 250 nm	굣
11	3	0.38	Hydrocortison	296 AU @ 250 nm	✓
12	3	0.53	Cortison	335 AU @ 247 nm	~
13	3	0.56	Corticosteron	343 AU @ 250 nm	✓
14	3	0,70	11_Dehydrocort	180 AU @ 246 nm	✓
15	3	0.84	11_Desoxicort	358 AU @ 250 nm	~
16	4	0.37	Hydrocortison	296 AU @ 250 nm	~
17	4	0.53	Cortison	332 AU @ 247 nm	~
18	4	0.56	Corticosteron	335 AU @ 249 nm	V
19	4	0.70	11_Dehydrocort	177 AU @ 246 nm	~
20	4	0.84	11_Desoxicort	360 AU @ 250 nm	V
21	5	0.37	Hydrocortison	280 AU @ 250 nm	V
22	5	0.52	Cortison	321 AU @ 247 nm	V
23	5	0.55	Corticosteron	333 AU @ 249 nm	V

(22) List of spectra for display

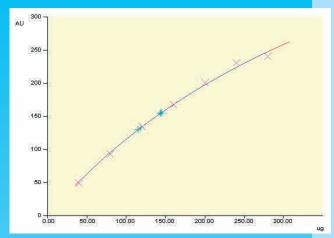


(23) View of selected spectra. Specific information on a selected spectrum can be obtained by clicking on it.

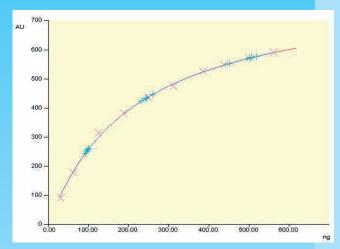
winCATS Options for TLC Scanner 3



(24) Linear regression



(25) Polynomial regression



(26) Michaelis Menten regression

Option Quantitative Evaluation

Quantitative evaluation is based on the comparison of peak heights or peak areas of the unknowns with those of calibration standards chromatographed on the same plate. Depending on the task at hand single-level or multi-level calibration can be selected.

Single-level calibration is suitable for analyses where the concentration of the unknowns shall be checked within narrow limits. Single-level calibration requires reduced calibration efforts.

Multi-level calibration is used when the target values are expected in a comparatively wide range.

winCATS offers a choice of four calibration functions, the selection is made based on which function gave the best result during method development.

Linear regression

Is a useful function when the calibration range is narrow or the absolute amounts per fraction are small, which often is the case when scanning by fluorescence.

Non-linear regression

Becomes necessary when a wider calibration range is needed and/or the absolute amounts per fraction are high. **winCATS** offers three kinds of nonlinear regression:

Polynomial regression

Is suitable for calibration over a wide concentration range with low amounts of substances.

Michaelis-Menten regression

Is suitable for calibration over a wide concentration range and for high amounts of substances. The Michaelis-Menten function defines an nonlinear relationship with a minimum number of standard levels. It can be used close to the saturation level of the detector.

The Michaelis-Menten function type 1 passes through the origin. In cases where this behavior is not suitable, Michaelis-Menten type 2 may be chosen.

Flexible input screens for calibration data *winCATS* offers a wide choice from entering "amount per fraction" to entering amounts from balance readings or from stock solutions.

According to the European and the American pharmacopoeia, related compounds can be quantified by comparison with small amounts of the main component in case their identification is not required.

This main-/sub-component evaluation is part of the standard quantitative evaluation program.

	Substance name	Rf	Window size [mm]	Regression mode	Deviation [%]	Purity
1	Rhodamine	0.23	0.8	Linear	0.0	1.000
2	Triamterene	0.40	0.8	Linear	0.0	1.000

(27) Definition of standard substances

	Stock Solution	Std. level1	Dim	Std. level2	Dim	Std. level3	Dim	Std. level4	Dim	Std. level5	Dim
1	Substance name										
2	Rhodamine	20.000	mg	20.000	mg	20.000	mg	20.000	mg	20.000	mg
3	Triamterene	4.000	mg	4.000	mg	4.000	mg	4.000	mg	4.000	mg
4	Preparation and dilution							0.10101010	and Aut		-
5	Volume solution	100,000	mL	100.000	mL	100,000	mL	100.000	mL	100,000	mL
7	Dilution from volume	1.000	mL	1,000	mL	1.000	mL	1.000	mL	1.000	mL
8	Dilution to yolume	100.000	mL	100.000	mL	100.000	mL	100.000	mL	100.000	mL
9	Application volume	2.000	μL	4.000	μL	6.000	μL	8,000	μL	10.000	μL
10	Vial	A1		A1		A1		A1		A1	

(28) Definition of standard levels using input from balance reading, solvent volumes and dilutions.

Sample from vial A3:	sample 1				
Result via height					
Substance	Rf	X(average)	CV [%]	n	Regression
Rhodamine	0.22	8.294 mg	1.266	2	Polynomial
Triamterene	0.35	1.713 mg	0.876	2	Linear
Result via area					
Substance	Rf	X(average)	CV [%]	T)	Regression
Rhodamine	0.22	8.333 mg	0.633	2	Polynomial
Triamterene	0.35	1.709 mg	1.715	2	Linear
Sample from vial A4:	sample 2				
Result via height.					
Substance	Rf	X(average)	CV [%]	n.	Regression
Rhodamine	0.22	9.889 mg	0.432	2	Polynomial
Triamterene	0.35	1.980 mg	0.213	2	Linear
Result via area					
Substance	Rf	X(average)	CV [%]	The state of the s	Regression
Rhodamine	0.22	9.976 mg	1.470	2	Polynomial
Triamterene	0.35	1.997 mg	0.059	2	Linear

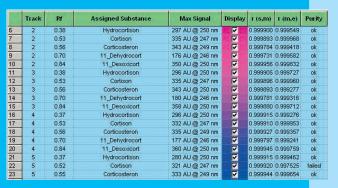
(29) Table of summary results per sample

Track	Vial	Rf	Amount / Fraction	Height	X(calc)	Area	X(calc)	Sample ID/Remark
1	A2	0.36		303.86	1.632 ng	3879.20	1.647 ng	sample 3
2	A1	0.36	800.00 pg	151.83		1932.35		
3	A2	0.36		300.64	1.614 ng	3823.87	1.622 ng	sample 3
4	A1	0.36	1,600 ng	308.28		3882.65		
5	A3	0.36		373.98	2.043 ng	4705.31	2.025 ng	sample 1
6	A1	0.36	2.400 ng	437.18		5542.22		
7	A3	0.36		378.33	2.069 ng	4813.90	2.075 ng	sample 1
8	A1	0.36	3.200 ng	576.78		7303.26		
9	A4	0.36		431.45	2.380 ng	5511.98	2.395 ng	sample 2
10	A1	0.37	4.000 ng	700.50		8955.21		
11	A4	0.37		430.23	2.373 ng	5516.33	2.397 ng	sample 2

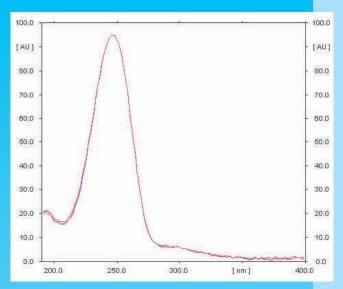
(30) Table of results per substance and track

	Substance name	Rf	Window size [mm]	Regression mode	Deviation [%]	Window type
1	Desethylatrazin	0.32	5.0	Polynomial	0.0	MainCom
2	Related 1	0.13	3.0	Polynomial	0.0	SubCom
3	Related 2	0.42	4.0	Polynomial	0.0	SubCom
4	Related 3	0.68	4.0	Polynomial	0.0	SubCom
5	Related 4	0.77	3.0	Polynomial	0.0	SubCom

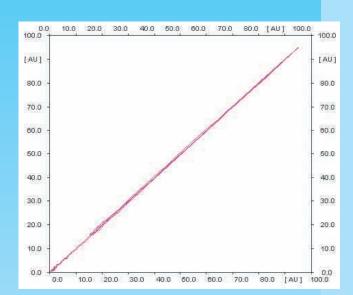
(31) Definition of standard substances in case of main-/sub-component evaluation



(32) List of spectra with correlation coefficients for peak identity and purity



(33) Spectra of an unknown and of a standard plotted superimposed



(34) Correlation plot for peak purity

Identity and purity check by spectra comparison

The option quantitative evaluation includes identity and purity check of fractions by spectra comparison. For identity checks spectra recorded at the peak maxima are compared with those of standard substances. The user can define a limit for the correlation coefficient, or let winCATS calculate identities by statistical criteria.

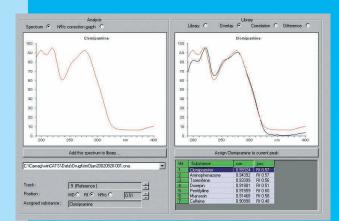
For checking the purity of a fraction, spectra are recorded at peak maximum and at both slopes. These spectra are then compared by winCATS either to match user specifications or according to statistical criteria.

Option Spectrum Library

Recording, displaying and comparing spectra of substances chromatographed on one plate is included in the standard scanner program. In order to compare spectra of substances chromatographed on different plates or to compare spectra with those of a spectra collection, the program option "Spectrum Library" is required.

The spectrum library can be used during substance assignment for validation of assigned substances as well as for identification of unknown fractions.

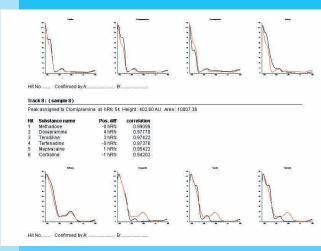
During the search process for identification the spectrum library shows a hit list of the closest substances including their spectra.



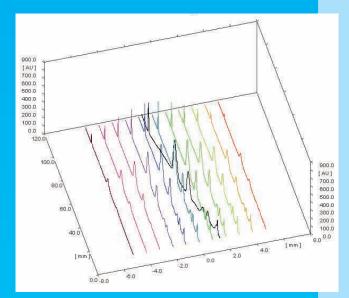
(35) Visual comparison: on the left a spectrum of the actual analysis together with a selection of characterizing parameters, on the right a hit list and the corresponding spectrum from the library. The user can select to plot the spectra superimposed as the difference between the selected spectra, or plot the correlation function only.

Option Volume of spectra

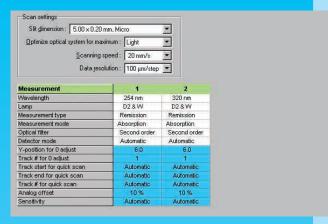
A collection of more than 600 spectra of basic, amphoteric and quaternary "street drugs" is available from CAMAG. It is suitable for screening in toxicological and forensic analysis, either independent or in combination with self recorded spectra.



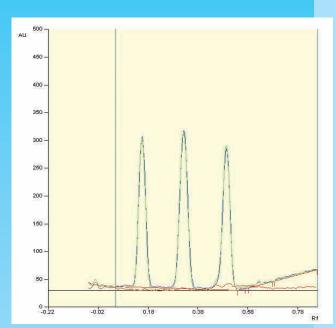
(36) Excerpt from a report including the hit list of all fractions.



(37) 3D view of results from track optimization



(38) Scan parameters for dual-wavelength scanning



(39) Dual-wavelength scan: the curve of the reference wavelength (red) is subtracted from that of the measuring wavelength (green). The resulting curve (blue) is available for integration and evaluation.

Option Track Optimization

With this program option a distorted chromatogram can be corrected.

Each track is scanned by a number of measurement passes, incrementally different in the X direction. The number of passes and their distance is selected according to the requirements of the particular chromatogram. After all scans of one track are completed, the software calculates the optimized track, i.e. from peak maximum to peak maximum. Only those data are then used for result calculation of the corrected chromatogram.

Note:

When used with chromatograms with proper alignment of fractions, the results obtained with or without track optimization are about the same.

In case of distorted chromatograms, results obtained with track optimization are comparable to those of a good chromatogram scanned without track optimization.

Prerequisites for improving the results of a distorted chromatogram are:

- a) The maxima of all peaks must be located within the area covered by the measurement passes.
- b) The change in peak shape caused by differences in migration distances, must not be too great.

For chromatograms with samples applied bandwise, i.e. by means of a Linomat, track optimization is not useful.

Option Dual-Wavelength Scan

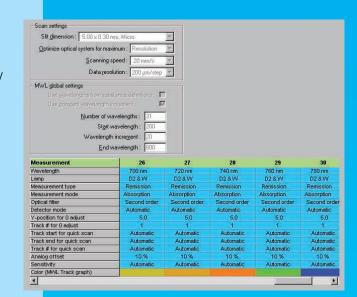
This option serves for background correction. The chromatogram is scanned with two wavelengths, the measuring and the reference wavelength, which each can be selected between 190 and 800 nm.

As the measuring wavelength one will usually select the wavelength of the absorption maximum of the substance to be calibrated. The reference wavelength should be sufficiently apart from this maximum absorbance in order to achieve good sensitivity, however, not too far away as otherwise irregularities in the layer will not be reliably compensated. A preceding recording of the spectrum is helpful for selecting the right combination of wavelengths.

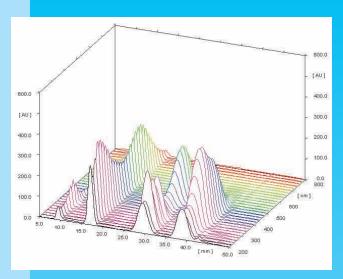
Option Multi-Wavelength Scan

The option multi-wavelength scan is an extremely useful tool for the quantitation of analyte mixtures whose components differ in their absorption maxima. The chromatogram on the plate can be scanned consecutively at up to 31 different wavelengths between 190 and 800 nm and the peak data stored in one analysis file. During the consecutive evaluation each component can now be automatically evaluated at its maximum absorbance. This way the user is relieved from manually evaluating the same plate at different wavelengths. This winCATS feature is unique in planar chromatography!

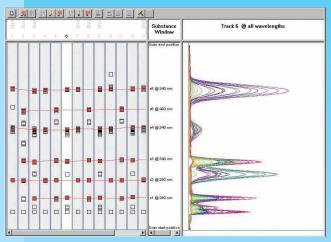
The 3D view of the multi-wavelength scan is another extremely helpful tool for identity checks. The 3D views can be scaled, swiveled and tilted, and then copied to clipboard or saved as a bitmap file for use in other software, e.g. Word.



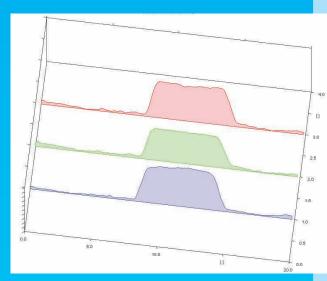
(40) Parameters for multi-wavelength scan, up to 31 wavelengths can be entered.



(41) 3D view of a multi-wavelength scan, here one track at all wavelengths



(42) Substance assignment: each peak is automatically assigned at its optimum wavelength before evaluation



(43) Example of slit illumination test: red curve shows uniformity of tungsten, green mercury and blue deuterium lamp

Qualification TLC Scanner 3	unit	lower limit	upper limit	detected	status
Basic electronics test					
Measuring electronics self diagnosis					passed
Main PM dark signal	mV	0.01	45.00	3.16	passed
Reference PM dark signal	mV	0.01	45.00	3.09	passed
PM match test : gain		10	50	32	passed
PM match test : high voltage	V	250	800	487	passed
PM relative sensitivity @ 400 nm	%	50.0	120.0	96.6	passed
Deuterium lamp tests					
Relative intensity	%	50.0	120.0	99.0	passed
Output noise	%	0.00	0.25	0.07	passed
Lateral adjustment	mm	9.91	10.23	10.07	passed
Slit illumination uniformity	%	90.0	100.0	97.8	passed
Equivalent burning time of this lamp	h	0.0	0.0	84.9	info only
Ignitions of this lamp		0	0	40	info only
Tungsten halogen lamp tests					
Output noise	%	0.00	0.25	0.08	passed
Lateral adjustment	mm	10.56	10.88	10.72	passed
Silt illumination uniformity	%	90.0	100.0	96.6	passed
Equivalent burning time of this lamp	h	0.0	0.0	971.1	info only
Ignitions of this lamp		0	0	256	info only
Mercury vapor lamp tests					
Relative intensity	%	50.0	120.0	108.2	passed
Output noise	%	0.00	0.25	0.18	passed
Lateral adjustment	mm	10.96	11.29	11.12	passed
Slit illumination uniformity	%	90.0	100.0	94.6	passed
Equivalent burning time of this lamp	h	0.0	0.0	12.1	info only
Ignitions of this lamp		0	0	4	info only
Monochromator tests					
Mercury line	nm	312.0	314.0	312.8	passed
Mercury line	nm	364.5	366.5	365.4	passed
Mercury line	nm	434.8	436.8	436.0	passed
Mercury line	nm	545.0	547.0	546.5	passed
Mercury line	nm	577.0	579.0	578.3	passed
Backlash (effective)	nm	0.00	1.00	0.24	passed
Bandwidth selector : position 1	nm	3.0	7.0	5.2	passed

(44) Screen with results from qualification

Option Scanner Qualification

With this option the TLC Scanner 3 can be automatically qualified and a report can be generated.

In the scanner qualification procedure the following checks are performed:

- Wavelength accuracy of the monochromator
- Stage positioning
- Condition and alignment of all lamps
- Condition and alignment of the optical system
- Condition of the electronic system

The complete qualification procedure can be carried out automatically or manually in sections. Certain deficiencies in lamp alignment and monochromator adjustment can be automatically corrected.

Example: The stage with the test pattern (straight line) is moved multiple times at 0.1 mm increments in Y direction across the slit. The resulting analog curve is evaluated by the program. This test gives information about:

- Uniformity of slit illumination with the respective lamp, and
- Correct alignment of the lamp and the optical system.

The result of each test is displayed on screen and can be printed as part of the qualification report. The report contains the target values and the values actually found together with a pass/fail judgment.

The option Scanner Qualification is required when the instrument shall be operated in a GxP environment.

Option 21 CFR Part 11 "compliance ready"

This option is required for compliance with the FDA regulation regarding the recording of electronic data and signatures. It includes:

- Safety of data acquisition and operation by user identification with password
- Secure storage of all results including raw data, complete data integrity and tracking
- Documentation of all activities in History Log/ Audit Trial for secure tracking
- Electronic signatures according to 21 CFR Part 11 requirements.



Instrument Qualification

IQ = **Installation Qualification** is performed at the site and at the time of installation. It documents that all specifications related to the safety requirements and the installation environment comply with the manufacturer's stipulations.

OQ = **Operation Qualification** is initially performed subsequently to installation and is repeated at intervals recommended by the manufacturer and/or defined by the customer. It documents that all modules of the equipment (system) function consistently within the specified operating ranges.

PQ = Performance Qualification certifies that the equipment (system) is suitable to perform a specific analytical task. It can thus only be performed by the user with his substances and according to his task description and test procedure following CAMAG's OQ and the respective instrument manuals.

CAMAG offers qualification according IQ/OQ and assistance with PQ as a service. Request information by fax or through our website **www.camag.com**

The winCATS option 21 CFR Part 11 "compliance ready" and the TLC Scanner 3 can be IQ/OQ qualified and then used in a GMP/GLP environment.



Ordering information

Densitometer, Software, Options, Accessories

- 027.6485 CAMAG TLC Scanner 3 for scanning by absorbance and fluorescence, equipped for objects up to 200×200 mm, wavelength range 190–800 nm, complete with deuterium lamp, tungsten-halogen lamp, and mercury vapor lamp, including Equilink to winCATS, but without winCATS license.
- 027.6420 Extension kit for scanning in transmission mode consisting of stage module, plug-in detector assembly and accessories

winCATS Program options:

- 027.6300 winCATS license inclusive 1 year of Internet update service
- 027.6315 Quantitative evaluation with winCATS
- 027.6342 Spectrum library
- 027.6349 Volume of Spectra "Basic and Quaternary Drugs"
- 027.6344 Track optimization
- 027.6346 Dual wavelength scan
- 027.6348 Multi wavelength scan
- 027.6340 Scanner qualification
- 027.6380 21 CFR Part 11 »compliance ready«

Special secondary filters:

- 027.6431 Sharp cut filter 340 nm
- 027.6433 Sharp cut filter 460 nm
- 027.6434 Sharp cut filter 500 nm
- 027.6436 Sharp cut filter 560 nm
- 027.6438 Narrow pass filter 360 nm
- 027.6439 Narrow pass filter 440 nm

The sharp cut filters 320 nm, 400 nm, and 540 nm are always shipped mounted on the filter wheel. They serve to eliminate second order wavelengths and can also be used as secondary filters.

Computer and accessories

Please note that we can offer a warranty for full functionality only for computers and operating systems tested and shipped by CAMAG, not for those generally declared to be compatible.



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