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Validation Manual Included

Every RapidTrace SPE Workstation comes with its own Validation Manual. This is a comprehensive document that includes detailed, step-by-step instructions to help you meet GLP, GMP and GCP requirements. Experienced Zymark consultants are available on a contract basis to assist with any validation assignment.



TurboVap® LV Workstation Is the Ideal Productivity Partner



Zymark's TurboVap LV Evaporation
Workstation offers "load it and leave it"
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Patented "gas vortex shearing" is 3–10
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We only succeed when you're successful

Zymark's Bioanalytical Group was formed specifically to meet the automation needs of pharmaceutical drug development, forensic and racing commission laboratories and contract research organizations.

As pioneers in the field of laboratory automation since 1981, Zymark has installed over 2,700 Zymate robotic systems, and thousands of workstation products throughout the world. We have built a business by forming unique partnerships with our customers, and promise you that all of our experience, expertise and effort will be applied to making your automation project successful.

The first step on the path to higher productivity starts with a phone call. To find out more about innovative Zymark Workstations for bioanalytical extractions, call (508) 435-9500 today.

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PRT 07/02

RapidTrace[®] SPE Workstation

Advanced bioanalytical techniques
like LC/MS/MS and GC/MS are meeting
the increasing demand for greater speed
and specificity in toxicological screening. But conventional sample preparation methods have not kept pace.
In particular, solid phase extraction
(SPE), an essential step in the analysis
of many biomolecules, has become a
throughput-limiting handicap in many
laboratories.

Zymark's RapidTrace SPE Workstation eliminates SPE bottlenecks, so that your lab can realize the full benefits of today's powerful—and costly—analytical instruments.

RapidTrace is the perfect complement to high-speed analytical techniques, a powerful, high-throughput workstation dedicated specifically to SPE bioextraction. In its full modular configuration, a single workstation can process 40–60, even 100, samples per hour!

Designed especially for the regulated pharmaceutical, clinical and forensic environment, RapidTrace is also a robust automated platform for quickly developing rugged, reliable SPE methods. These procedures can be easily transferred from workstation to workstation, from site to site, or from the pharmaceutical lab to an outside Contract Research Organization.



Automated High Throughput SPE Extraction

Increased Throughput for Routine Sample Handling

Your SPE processes can keep up with your analytical capabilities. Plus, the modular design of the RapidTrace workstation lets you add capacity as required; for example, as a compound moves from initial toxicology screening into more formal pre-clinical studies and then into human clinical trials.

Accelerated Methods Development & Optimization

Using a friendly, familiar Windows interface, you can easily implement a structured, "rational" strategy for SPE experiments to determine optimum SPE conditions for each of your samples.

Readily Transferable Methods

Methods stored in the RapidTrace controller can be instantly recalled, and can be transferred to other RapidTrace workstations with 100% confidence.

"Parallel Processing" Assures Maximum Productivity

Each module operates independently. So if one is shut down for operator attention, the others stay on-line.

Improved Operator Safety

Zymark's automated approach improves lab safety by minimizing operator contact with hazardous samples and chemicals.

Validation Documentation Included with Each Workstation Better Analytical Results

Finally, RapidTrace provides the consistently clean extracts that sophisticated analytical instruments like LC/MS/MS and GC/MS require for optimum performance.

Now your sample prep can keep up with your analytical instruments.

Modular Design Maximizes Throughput and

Rational Methods Development

Unmatched Performance and Throughput

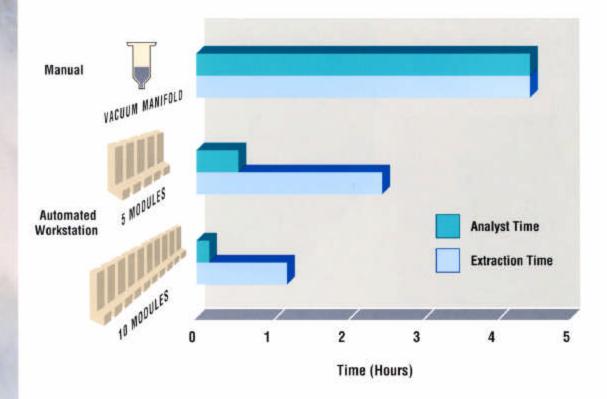
RapidTrace eliminates tedious and time-consuming manual bioextraction methods. Every step of the SPE process is automated and rigorously controlled, to give you a level of reproducibility that simply can't be obtained with conventional techniques.

Capable of handling up to ten samples/module, a 10 module
RapidTrace Workstation delivers the throughput a busy lab needs to keep up with 2–5 minute LC/MS/MS cycle times.

- Modular design lets you add throughput capability as required—up to 100 samples per run at up to 100 SPE samples per hour! Modules within a group can run different methods. Or, modules can be separated and even used in different labs.
- All sample and solvent flow rates are individually controlled under positive pressure.
 You'll improve results by optimizing each step of the SPE process for maximum accuracy and precision (something you can't do with a conventional vacuum manifold).
- You can program individual modules and even individual samples with different conditions to speed development and test methods for ruggedness and reliability.

Improved Throughput and Workflow

In one lab using a RapidTrace Workstation versus a vacuum manifold to extract 75 samples, there was a 93% reduction in analyst time and a 72% reduction in extraction time.

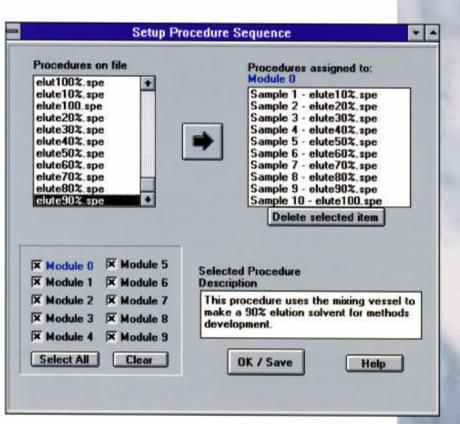


Optimizing Extraction Strategies

Automated SPE Methods Speed Assay Development

Developing an HPLC assay for an investigational peptide, a high-throughput drug metabolism laboratory used SPE techniques to isolate the peptide and an internal standard from rat plasma. The RapidTrace Workstation allowed them to develop an optimized extraction strategy in a fraction of the time required by conventional bench methods.

By applying stored methods to a series of samples, and selectively varying extraction conditions, the lab was able to achieve analyte recovery of about 85% (compared with the previous 60–65%), with no loss of precision. Based on these results, the RapidTrace methods were later extended to human samples, and showed excellent accuracy and precision over a standard curve range of 2.5–2500 ng/mL.



Recovery Data for RapidTrace SPE Extraction Method of Investigational Peptide in Human Plasma					
Concentration Range of Standard (ng/ml.)	Mean Concentration Found (n=5) (ng/mL)	% Recovery			
2.5	2.47	99%			
5.0	5.07	101%			
10.0	10.2	102%			
25.0	25.4	102%			
50.0	50.7	101%			
100.0	95.3	95%			
250.0	248.0	99%			
500.0	519.5	104%			
1000.0	1042.5	104%			
1750.0	1735.7	99%			
2500.0	2448.5	98%			



RapidTrace Controller provides direct PC control with either desktop or laptop PC.



Modular, small-footprint

design saves valuable

bench space.

Ten 13 x 100 mm sample input tubes in each RapidTrace module allow simultaneous processing of up to ten SPE samples.

Locations for ten 12 x 75 mm fraction collection tubes (adapters available for HPLC and GC sample vials) allowing for collection of up to 10 fractions/sample.

> Reagent mixing chamber allows automated on-line reagent blending within the method.

Positive pressure, computercontrolled syringe drive provides precise, accurate flow rates for each step in the SPE process.

Eight solvent / reagent lines for maximum methods flexibility.

Closed fluid path system with for the SPE column, one for



segregated waste lines (three the sampling cannula).



Ten-position SPE column turret accepts any 3 mL or 1 mL syringe barrel SPE columns (adapters available for SPE disks or soft gel cartridges).

Multiple built-in sensors constantly scan each module. If a problem is detected, only the affected module automated, "hands-off" handling of routine samples (chilled racks

are also available).

Improved Productivity

New Drug Candidate Plasma Studies

Pharmaceutical Lab Improves **Productivity and Reduces Assay Costs**

A large pharmaceutical company required analytical data on plasma levels for a new drug candidate in early phase clinical trials. Considered a "routine" analysis, the sample load was outsourced to a contract lab.

In an effort to improve turnaround time and reduce costs, the lab turned to RapidTrace SPE automation. The original method, developed using 3 mL SPE cartridges on a vacuum box, was transferred to the automated unit, further optimized, and quickly validated. Within days, the 10-module RapidTrace workstation was on-line, delivering a faster, more reliable assay and considerable savings in time and labor.

Dri	ug in Plasma Extraction	
Item	RapidTrace (10 Modules)	Vacuum Manifold
# of Manual steps to run a sample	5	17
Time to run 75 samples	1 Hour	4.5 Hours
% Failures	0%	15%
# of Runs required for 75 sample batch	1 Run	3 Runs
# of Standards and controls for 75 sample batch	5	15
Operator time	0.3 Hour	4.5 Hours

High Sample Throughput Assay

Screening for Cocaine Metabolite (BZE)

Drug Testing Lab Processes 56 Samples/Hour with High Reliability

A common test for drugs of abuse is screening urine for the presence of Benzoylecgonine (BZE) for confirmation by GC/MS. The SPE cleanup is labor intensive, and, using conventional vacuum manifold methods, is highly susceptible to operator variations.

To bring the process under control, to improve lab throughput and to reduce analysis costs, a contract testing lab automated the procedure using a RapidTrace Workstation. The automatic procedure can be run in just 11 minutes; on the lab's 10-module Workstation, it now takes less than two hours to process 100 samples!

Ste	p	Source	Destination	Volume (mL)	Flow (mL/sec
1	Condition	MeOH	Waste 2	3.0	.30
2	Condition	diH ₂ 0	Waste 1	3.0	.30
3	Condition	pH6	Waste 1	3.0	.30
4	Load	Sample	Waste 1	4.0	.04
5	Pause	=	Time = 0.1	minute	
6	Purge-Cannula	diH ₂ 0	Cannula	4.0	.40
7	Rinse	diH ₂ 0	Waste 1	3.0	.15
8	Rinse	H,PO,	Waste 1	3.0	.15
9	Rinse	MeOH	Waste 2	3.0	.15
10	Rinse	Vent	Waste 1	5.0	.30
11	Collect	Mixed	Fraction 1	3.0	.20
12	Rinse	Mixed	Waste 2	2.5	.20
13	Rinse	MeOH	Waste 2	2.5	.20
14	Purge-Cannula	MeOH	Cannula	3.0	.40
15	Purge-Cannula	diH _s 0	Cannula	3.0	.40

Within Run								
Control Target Value (ng/mL)	1	2	Sample # 3	4	5	Mean	C.V. (%)	Avg. Recovery
120	113	118	120	119	113	117	2.9	97.5%
180	182	176	186	176	174	179	2.8	99.4%
Run-To-Run					7 7			
Control Target Value (ng/mL)	1	2	Run #	4	5	Mean	C.V. (%)	Avg. Recovery
113	117	117	119	122	124	120	2.4	106.2%
Linearity R ² = 0.9999	(75-1000 ng.	/mL)						

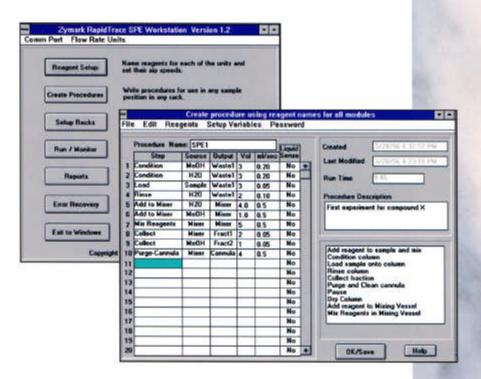
Accelerates New Methods Development

Fast and Easy Development of "Bullet-Proof" Methods

Because you can write methods in minutes (and call them up in seconds), you can optimize your SPE conditions in a fraction of the time required using conventional techniques. Column types, reagents, concentrations and flow rates can be thoroughly explored; for example, you can vary a single parameter (pH, percent solvent, cartridge type, flow rate, etc.) incrementally to see its affect on recovery and precision. This unique "rational SPE design" capability dramatically speeds the development of rugged, reliable methods.

The familiar Windows™ interface makes methods set up and editing as easy as "point and click." Simply select an operation, then enter the desired reagent, reagent volume and flow rate; each of these parameters can be defined independently for each step. As each operation is selected, RapidTrace automatically adds it to the procedure.

Editing methods is just as easy. You can insert, delete or change steps, or adjust any of the parameters. Methods can be assigned to an individual sample or by module. They can be saved and run together for true "multi-method" SPE, in an unattended run.



Methods Sharing Is Easy, Too

SPE by conventional techniques is often more art than science. Results can vary considerably, depending upon the skill of the analyst, even when the "same" method is used.

The RapidTrace Workstation automates every step in the extraction procedure, to give you robust, 100% reproducible methods that you can confidently hand off to any other RapidTrace Workstation—across the hall, or around the world.

Built-In On-line Support

The RapidTrace Workstation also includes a built-in modem, plus software that gives Zymark's applications support staff the data they need to provide fast, accurate on-line troubleshooting. Most problems can be handled over the phone, but if an individual module should require service, it can be removed—while the others keep on working.

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