

Pharmaceutical

Restek Chromatography Products

2011 Overview



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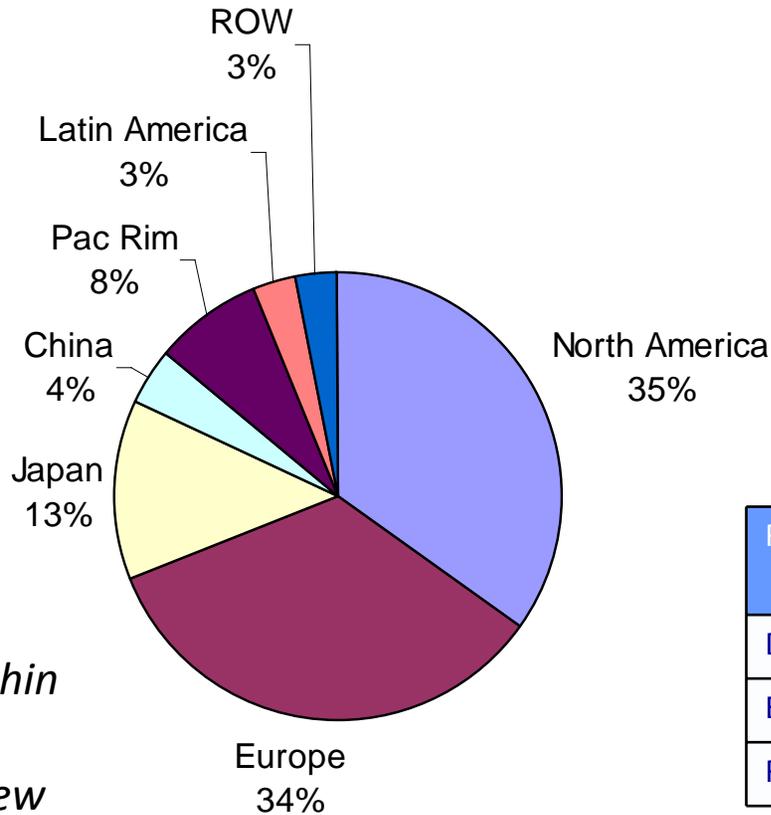
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Outline

- Market trends
- Pharmaceutical Products for HPLC
- Pharmaceutical Products for GC

Liquid Chromatography Consumables Market by Geography



Region	Percentage	Estimated TAM
Domestic US	35%	245
Europe	34%	238*
ROW	31%	217

* Potentially inflated by currency translation



Large market opportunity within Restek reach, especially for new technology

2007 SDI Market Forecast

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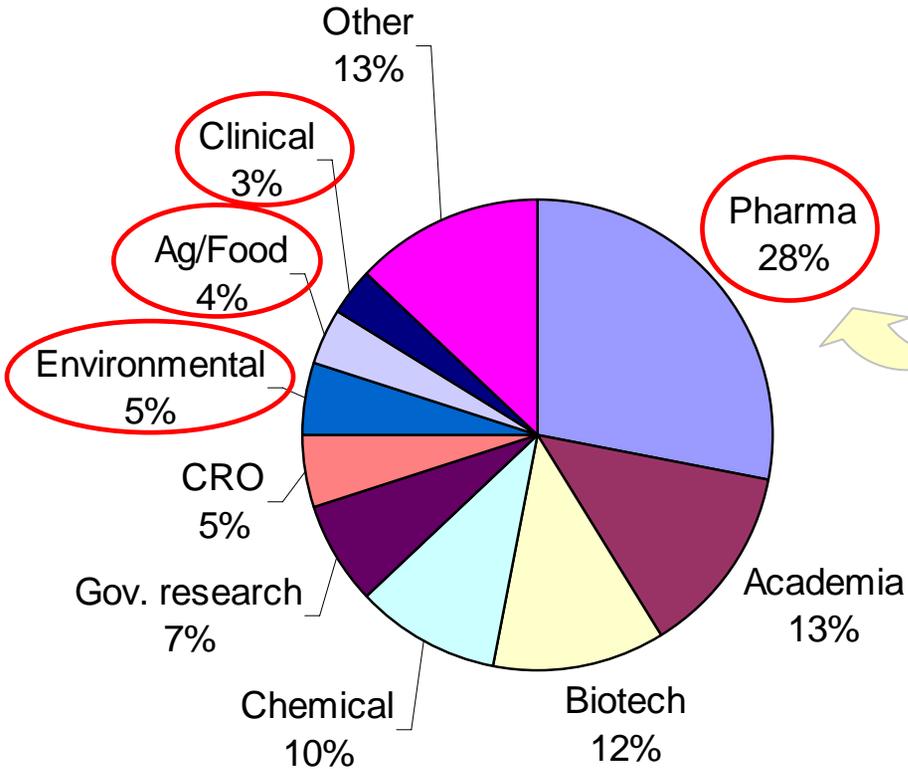
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Liquid Chromatography Consumables Market by Industry

2007 HPLC Demand by Industry



Pharma is a major user of LC



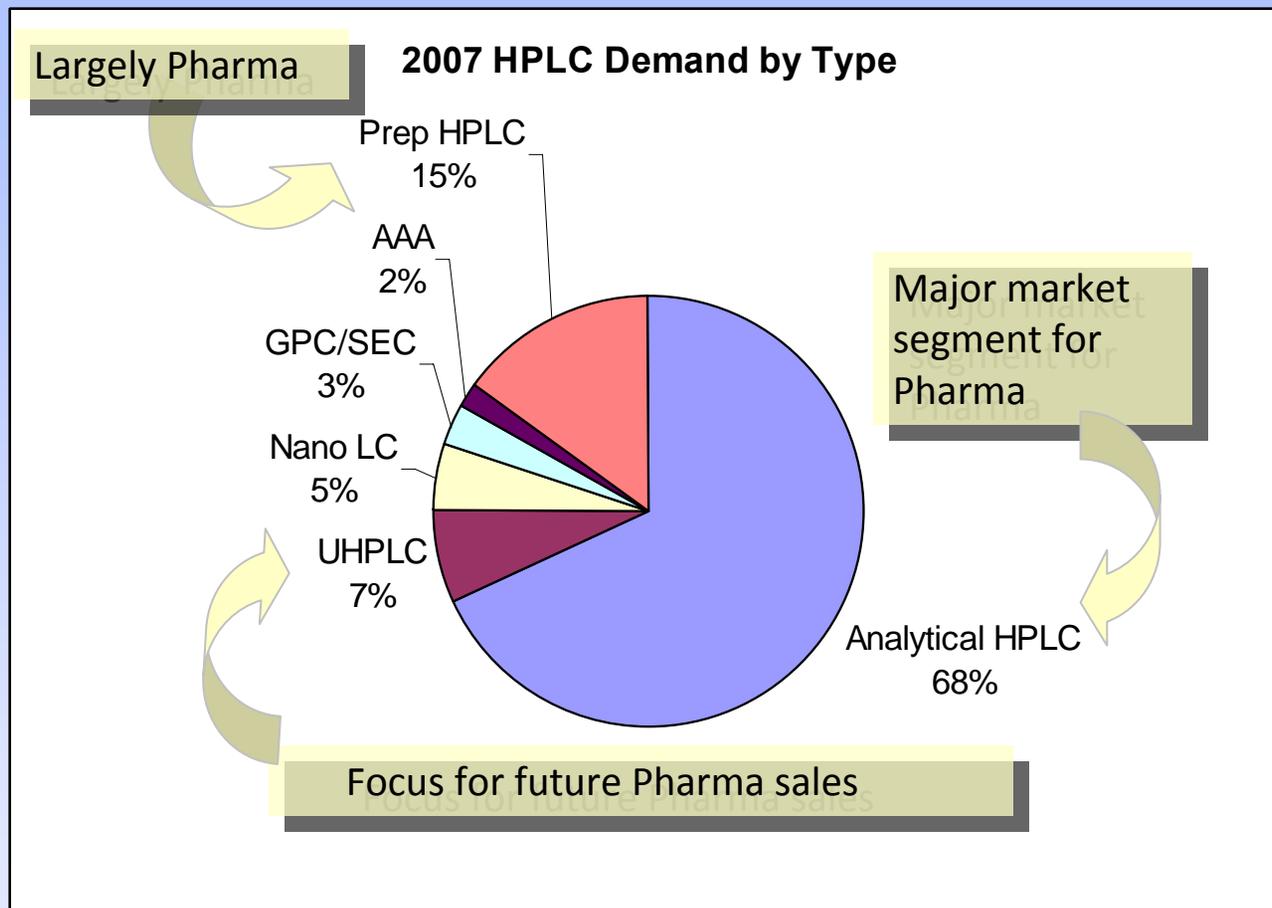
Opportunity to expand our industry reach and focus –

- Ag/Food
- Clinical
- Environmental

2007 SDI Market Forecast

* Potentially inflated by currency translation

Market Assessment – HPLC Demand



2007 SDI Market Forecast

Technology Focus - Mass Spectrometry

SDI data on analytical instrument technology shows mass spectrometry is a **\$3B** market and predicts...

Table V-2: Demand by Analytical Instruments Technology, 2005-2010

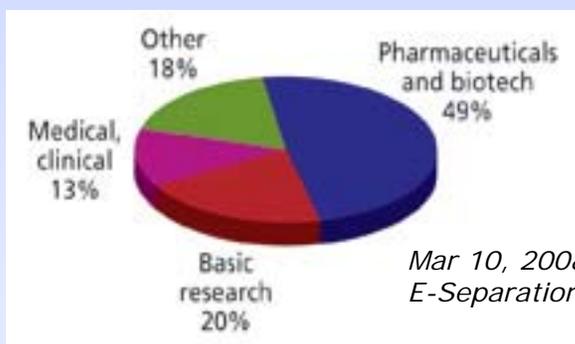
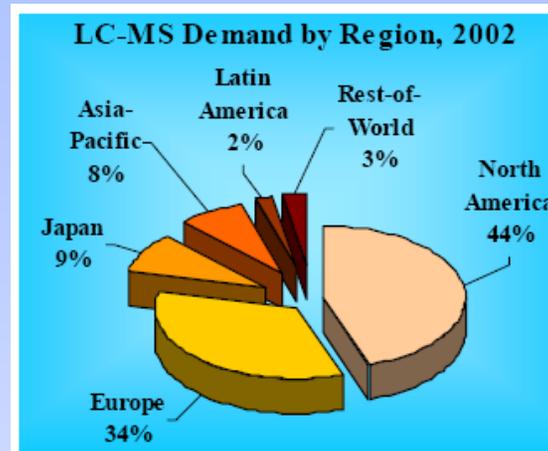
	2005		2006		2007		2010		'05-'10 CGR
	\$ Mil	Percent							
Separations	5,248	17%	5,529	17%	5,812	17%	6,666	16%	4.9%
Life Science Instrumentation	7,943	26%	8,529	26%	9,119	26%	10,815	26%	6.4%
Mass Spectrometry	1,809	6%	1,976	6%	2,146	6%	2,700	7%	8.3%
Molecular Spectroscopy	2,745	9%	2,908	9%	3,087	9%	3,700	9%	6.2%
Atomic Spectroscopy	2,207	7%	2,364	7%	2,495	7%	2,786	7%	4.8%
Surface Science	3,771	12%	4,019	12%	4,274	12%	5,198	13%	6.6%
Materials Characterization	1,803	6%	1,910	6%	2,023	6%	2,368	6%	5.6%
Laboratory Automation	2,669	9%	2,873	9%	3,082	9%	3,770	9%	7.2%
General Lab Instrumentation	2,610	8%	2,702	8%	2,798	8%	3,102	8%	3.5%
Total	30,805	100%	32,810	100%	34,836	100%	41,106	100%	5.9%

...that it will have fastest growth rate (8.3%) of any analytical instrument technology

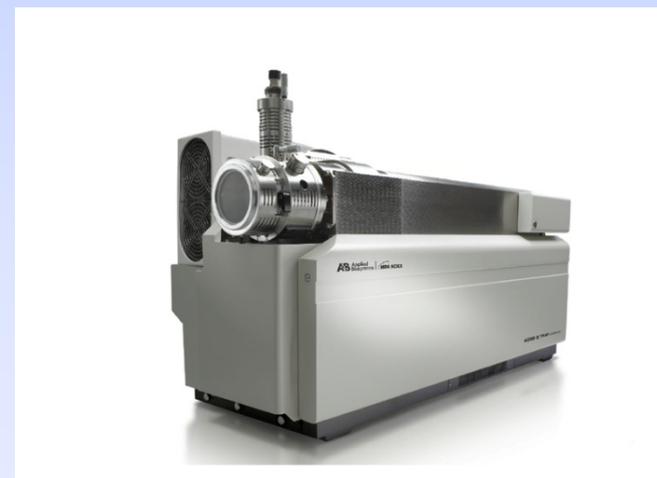
Technology Focus - Mass Spectrometry

The use of Mass Spectrometry is creating industry growth opportunities

Industry	Percentage	Trending
Pharmaceutical and Biotech	49%	↓
Clinical	13%	↑↑
Basic Research	20%	↓
Environmental	18%	↑
Petroleum		
Forensics		
Food		



Mar 10, 2008
E-Separation Solutions

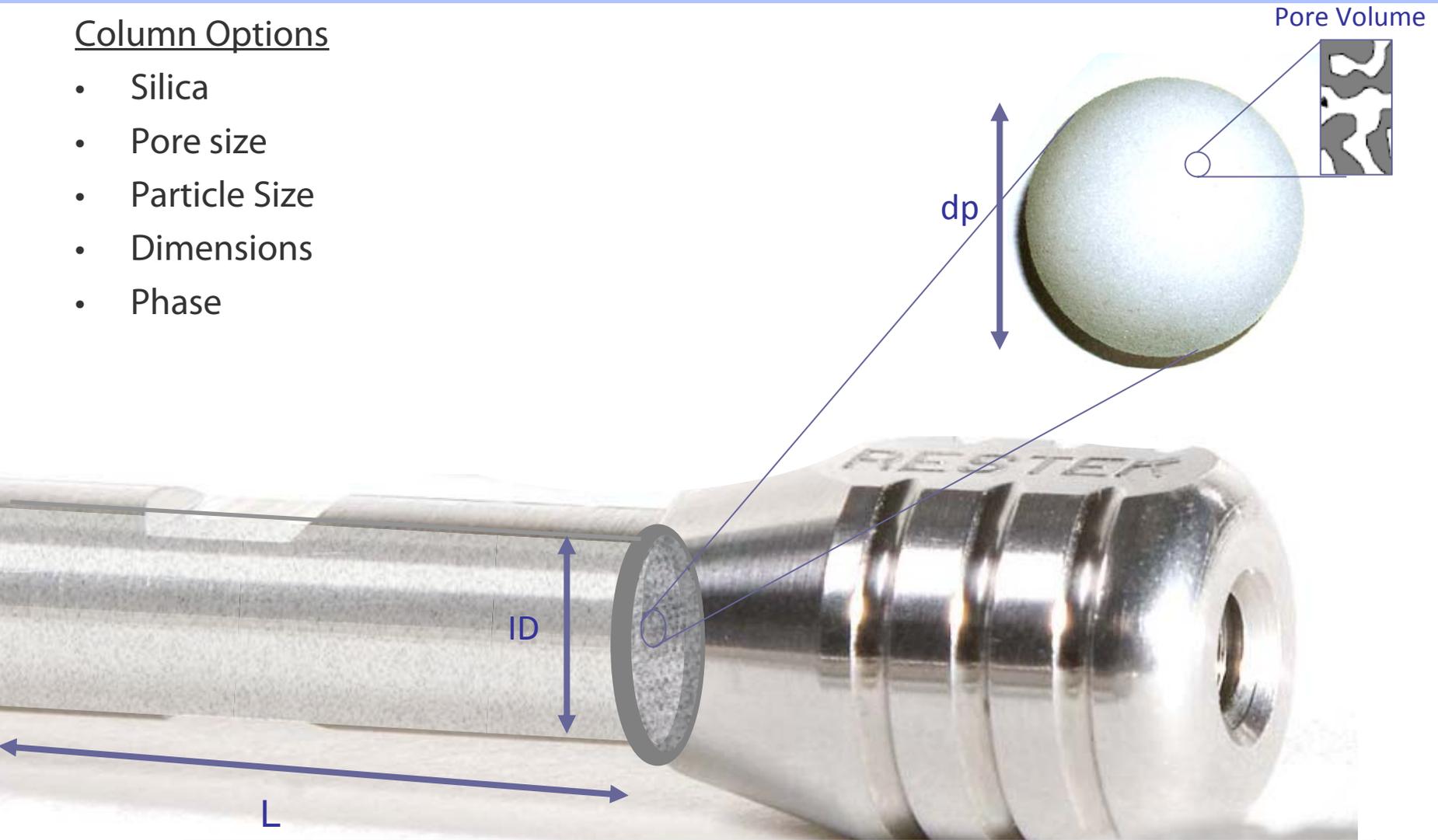


Focus product development and applications on MS

Determining Column Format

Column Options

- Silica
- Pore size
- Particle Size
- Dimensions
- Phase



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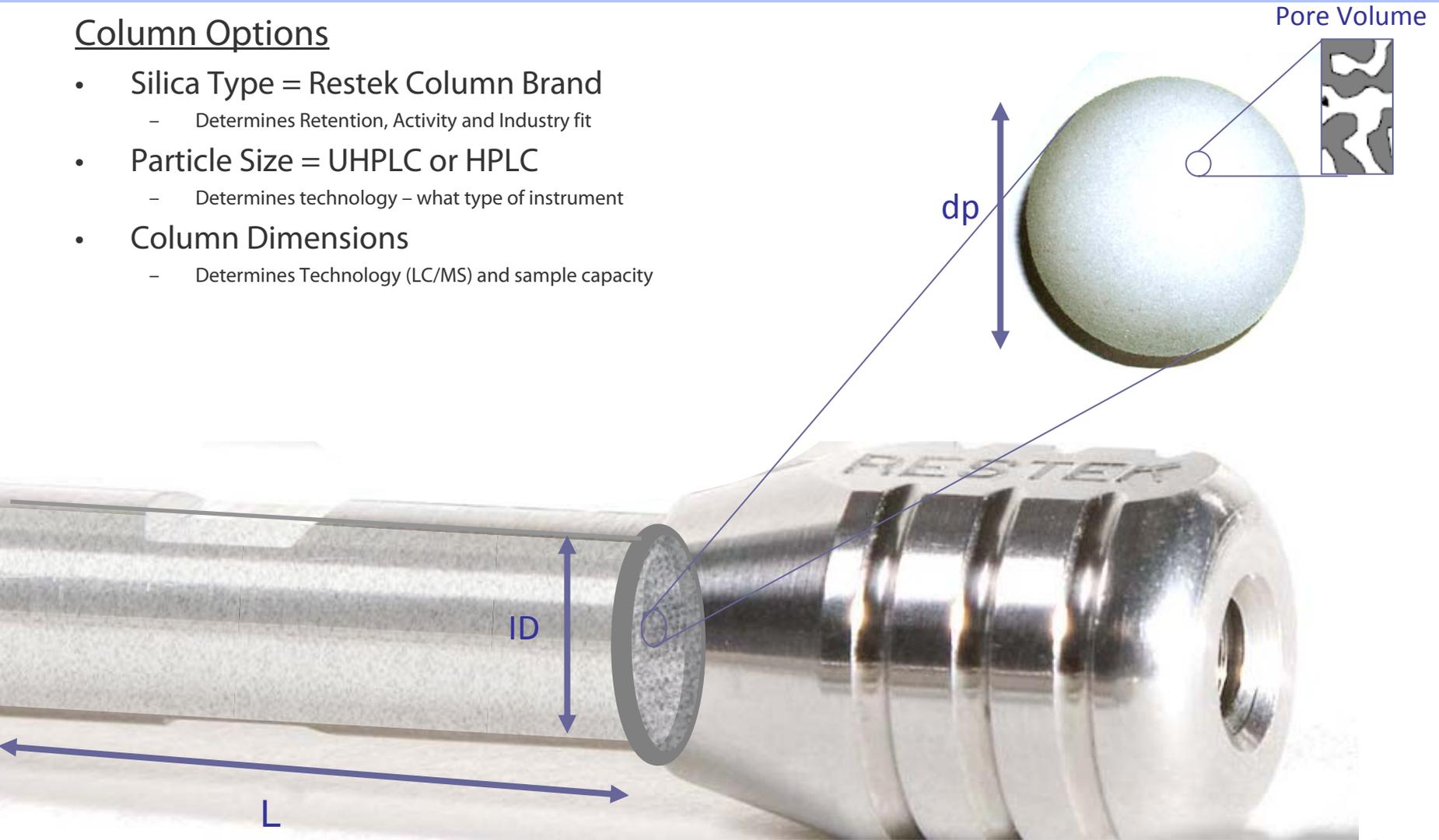
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Determining Column Format

Column Options

- Silica Type = Restek Column Brand
 - Determines Retention, Activity and Industry fit
- Particle Size = UHPLC or HPLC
 - Determines technology – what type of instrument
- Column Dimensions
 - Determines Technology (LC/MS) and sample capacity



Restek High Purity LC Column Lines

Column Line	Pore Size (Å)	Surface Area (m ² /g)	Carbon Load (%)	Usage
Allure	60	450	27	<u>Very high retention</u> (highest convectional C18 in market) High Purity Type B (super low metal content) 5 um particle size only (type B)
Ultra**	100	300	20	<u>High Retention</u> High Purity Type B (super low metal content) 3 and 5um particle size only
Pinnacle DB**	140	150	11	Mid- Retention Base Deactivated 1.9, 3 and 5um particle sizes UHPLC and HPLC

Good recommendations for all markets, including pharmaceutical

Restek LC Column Lines

Column Line	Pore Size (Å)	Surface Area (m ² /g)	Carbon Load (%)	Usage
Pinnacle II	110	180	13	Mid – Retention Acidic Silica (not for Reversed Phase in Pharma) 3 and 5µm particle size only

Type A Economical Silica – NOT intended for sale in the pharmaceutical market

Particle Size to Instrument Fit Chart

Manufacturer	Model	Recommended Particle Size (µm)	Recommended ID (mm)
Waters	Alliance	5 and 3	4.6 and 3.2
Waters	Acquity	1.9	2.1
Agilent	1100	5 and 3	4.6 and 3.2
Agilent	1200	5,3 (and 2.2)	4.6, 3.2 (and 3.0)
Agilent	1290	1.9	2.1
Shimadzu	Prominence	5 and 3	4.6 and 3.2
Shimadzu	UFLC XR	2.2	3.0
Shimadzu	Nexera	1.9	2.1
Jasco	XLC	1.9	2.1
Hitachi	La Chrom Elite	5 and 3	4.6 and 3.2
Hitachi	La Chrom Ultra	1.9	2.1
Dionex	Ultimate 3000	5 and 3	4.6 and 3.2
Dionex	Ultimate 3000 RS	1.9	2.1
Perkin Elmer	Flexar	1.9	2.1
Thermo	Accela	1.9	2.1

Capillary Columns Available

Becoming popular for Bio Analytical and Bio Pharma applications

Phase	Pore Size (Å)	ID (mm)	Length (mm)
Ultra Aqueous C18	100	0.3	50
Ultra Aqueous C18	100	0.3	150
Ultra C18	100	0.3	50
Ultra C18	100	0.3	150
Viva C18	300	0.3	50
Viva C18	300	0.3	150



Restek Reversed Phase Column Listing

Phase Type	Phase Type	Usage
C1 through C18	Conventional Alkyls	General Purpose Alkyl Phases
Aqueous C18 ★	"Aqueous"	<ul style="list-style-type: none"> • <u>Balanced Retention</u> (retains the widest range of compounds) • 100% compatibility with aqueous mobile phases – no de-wetting • Great for drug discovery and LC/MS/MS C18 • <u>Rugged</u>
AK ★	Combined Alkyl and Phenyl Properties	Intermediate C18 and Phenyl Selectivity
Phenyl	Conventional Phenyl	General purpose phenyl
Biphenyl ★	Advanced "special" Phenyl	<ul style="list-style-type: none"> • <u>Higher retention and selectivity than phenyl</u> • Great for aromatic or unsaturated compounds • Increased selectivity when compared to phenyl hexyl and diphenyl
Aromax ★	Maximum Aromatic Selectivity	<ul style="list-style-type: none"> • Specialty phenyl for maximum aromatic selectivity • High retention for LC/MS/MS in DMPK

★ Unique

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Restek Reversed Phase Column Listing

Phase Type	Phase Type	Usage
IBD ★	Polar Embedded	<ul style="list-style-type: none"> •RP and HILIC Modes •Great for DMPK (retention of polar acids) and QA/QC (excellent peak shape of bases) •Lessens needs for mobile phase modifiers
PFP	Fluorinated	<i>Not to be recommended over PFP Propyl unless PFP Propyl shows too much retention</i>
PFP Propyl	Fluorinated	<ul style="list-style-type: none"> •RP and HILIC Modes •Great for DMPK (retention of protonated bases and halogenated compounds) •Typically more versatile than Cyano columns in pH range •Lessens need for mobile phase modifiers
Amino	Amino	Traditional chemistry, highly used for the analysis of saccharides and sugars
Cyano	Cyano	Traditional column chemistry for the increased retention and selectivity of protonated bases

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Multi Modal Analysis of 4-Methylimidazole (4MI or 4-MEI)

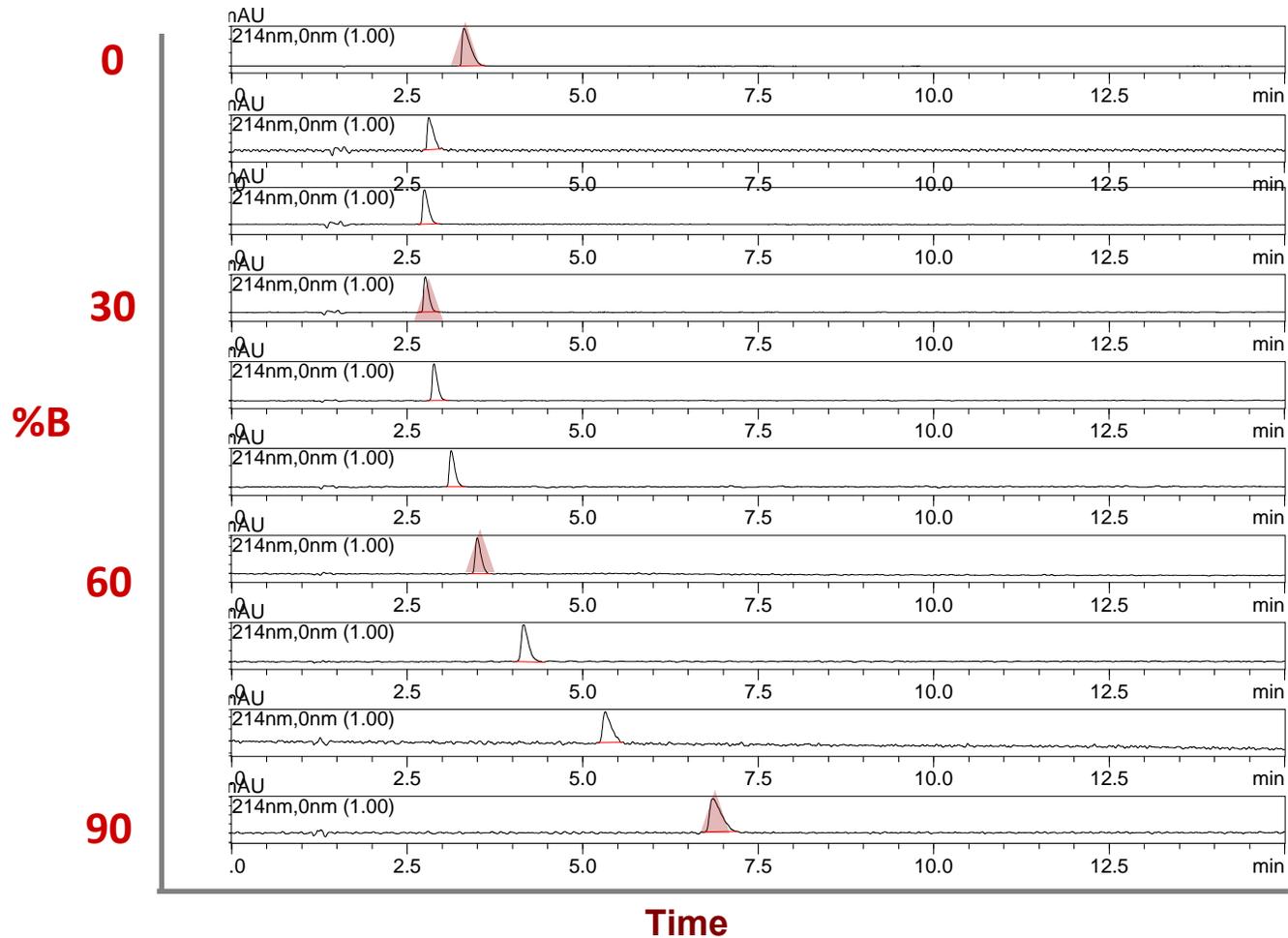
Ultra PFP Propyl
4.6 x 150mm,
5µm

1.5 mL/min,

30°C

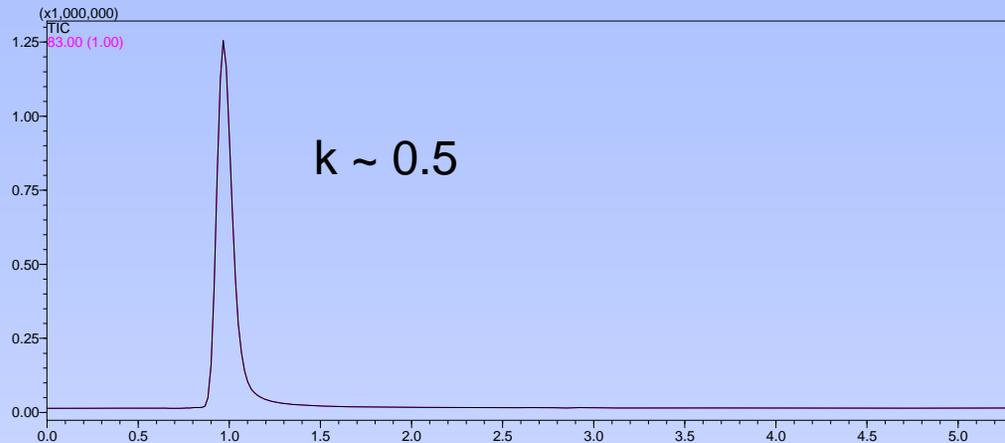
A: 0.1% formic
acid in water

B: 0.1% formic
acid in Methanol

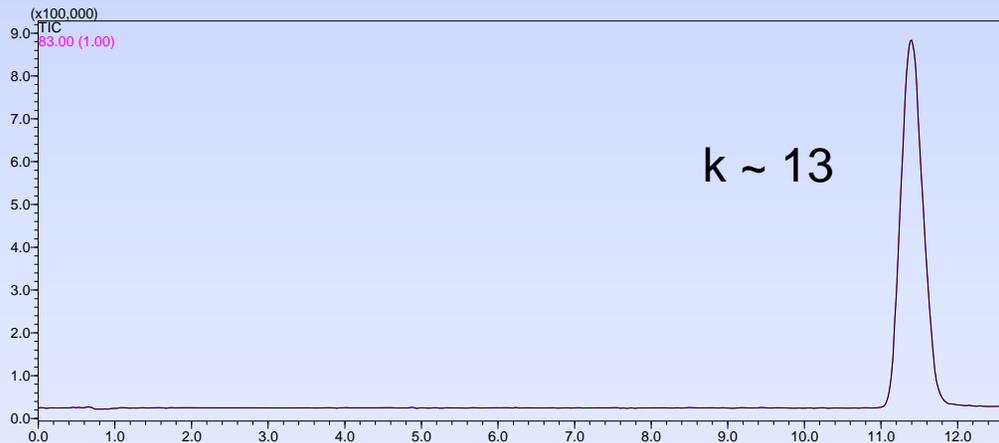


HILIC Retention

Ultra Silica
2.1 x 100mm, 3 μ m
0.4mL/min
80% MeOH
20% 10mM ammonium formate in water
30°C
1 μ L injection
10 μ g/mL in 0.1% formic acid in water
SIM m/z=83



Ultra PFPP
2.1 x 100mm, 3 μ m
0.4mL/min
30% Water w/ 0.02% formic acid
70% MeOH w/ 0.02% formic acid
30°C
1 μ L injection
10 μ g/mL in 0.1% formic acid in water
SIM m/z=83



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Restek Normal Phase / HILIC Column Listing

Phase Type	Phase Type	Usage
IBD	Polar Embedded	<ul style="list-style-type: none"> •Can be used on NPC and HILIC modes •Excellent selling point for DMPK (RP and HILIC modes)
PFP	Fluorinated	<i>Not to recommended over PFP Propyl unless PFPP shows too much retention</i>
PFP Propyl	Fluorinated	<ul style="list-style-type: none"> •Can be used on NPC and HILIC modes •Excellent selling point for DMPK (RP and HILIC modes)
Amino	Amino	General purpose NPC / HILIC
Cyano	Cyano	General purpose NPC / HILIC
Silica	Silica	General purpose NPC / HILIC

Restek UHPLC

•Features

- Widest Variety of Stationary Phases
- Cost – Effective
- Improved Lifetime – innovative hardware design
- Restek Manufactured Silica – total control



Actual E-mail Customer response :

" Darrel,

Just wanted to let you know we retired one of your uplc columns today. The column had over 13,000 injections on it and still passed all system suitability requirement. Just getting a little close. Just thought I'd give you a shout. Feel free to use that as an example to any potential customers if you want

*- Manager of Quality Control,
Mylan Pharmaceuticals "*

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Pinnacle DB UHPLC Columns

COLUMNS TESTED: UPLC® HSS T3 1.8 mm, 2.1/50 MM (Waters Corporation),
Acquity UPLC® BEH C18 1.7 mm, 2.1/100 mm (Waters Corporation)
 **Pinnacle DB C18 1.9 mm, 2.1/50 mm (Restek U.S.)**
VisionHT C18-P 1.5 mm, 2.0/50 mm (Grace)
Hypersil GOLD 1.9 mm, 2.1/50mm (Thermo Scientific)

using a validated (Bioanalytical method validation by FDA 2001) in GLP environment and OECD audited method.

Title of article is:

APPLICATION OF ULTRA PERFORMANCE COLUMNS IN HIGH PERFORMANCE LIQUID CHROMATOGRAPHY FOR ALBENDAZOLE AND ITS METABOLITES DETERMINATION IN TURKEYS

Tomasz Grabowski a, Jerzy Jan Jaroszewski b , Anna Świerczewska a, Renata Sawicka a, Tomasz Maślanka b, Włodzimierz Markiewicz b, Hubert Ziółkowski b

a Centre of Pharmacokinetics Research FILAB, Ravimed Sp. z o.o., Łajski, (Poland)

b Department of Pharmacology and Toxicology, Faculty of Veterinary Medicine, University of Warmia and Mazury, Olsztyn, (Poland)

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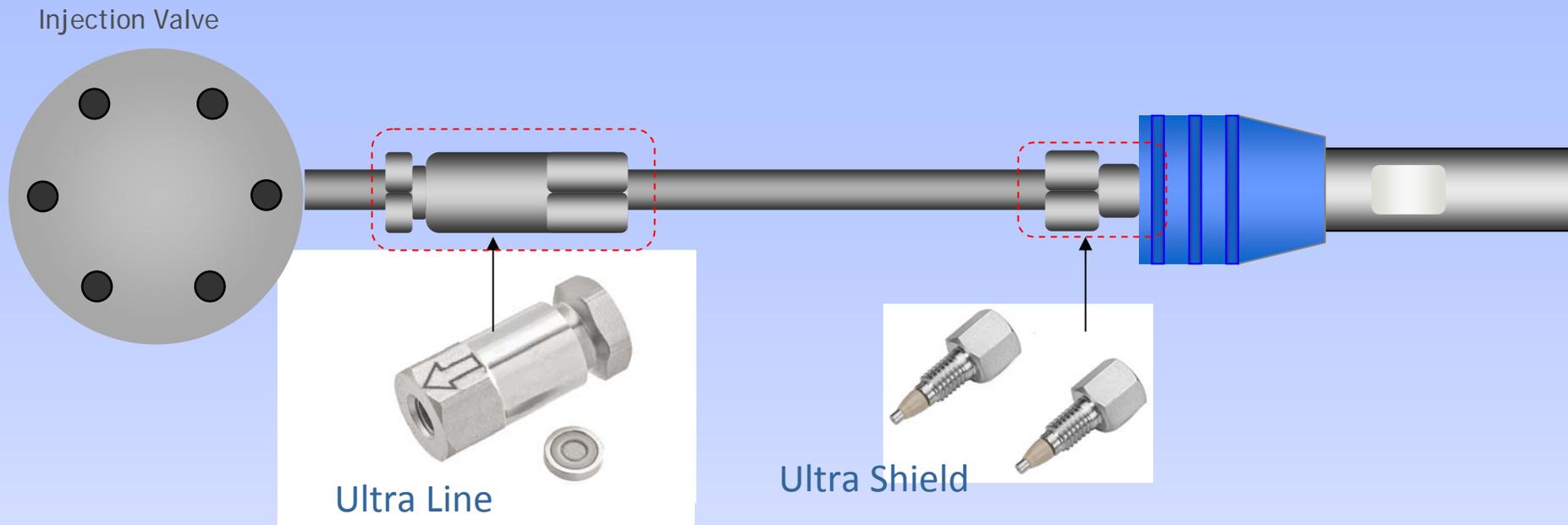
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Proper Filtration for UHPLC



**Install 0.5um Ultra Line or
0.5um Ultra Shield**

- Will not stop matrix
- Guard columns add volume and losses in efficiency
- 0.00625mm tubing compared to 0.175mm tubing for HPLC

Product Focus



- USLC is the use of *Selectivity* on any instrument platform
- USLC phases offer the widest variety of selectivity for effective and fast method development
- USLC phases define a simple approach to column selection
- USLC offers a simplified product offering for column recommendations

Restek Product Positioning



Discover Restek USLC™
Develop Methods Quickly and Easily Using Ultra Selective Chromatography

Ultra Selective Liquid Chromatography™

What is Ultra Selective Liquid Chromatography™? USLC™ is the directed application of selectivity—the most influential factor affecting resolution—to optimize separations and improve method performance. Restek has extensively studied reversed phase selectivity to provide practicing chromatographers with the most effective and widest range of USLC™ stationary phase chemistries available.

This is independent of column line. It differentiates our phases, not our column lines

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Competitive Column Offerings

Figure 3: Restek offers the widest range of phase selectivities for HPLC and UHPLC.

Column Type	Column Line								
	Restek			Waters			Phenomenex	Agilent	
	Pinnacle DB	Ultra	Viva	Acquity CSH	Acquity HSS	Acquity BEH	Kinetex	Zorbax RRHD	Poroshell 120
Alkyl (C18 and C8)	●	●	●	●	●	●	●	●	●
Phenyl	●	●	●	●		●			
Polar Embedded Alkyl	●	●	●						
Fluorophenyl	●	●	●	●			●		

We have them all!

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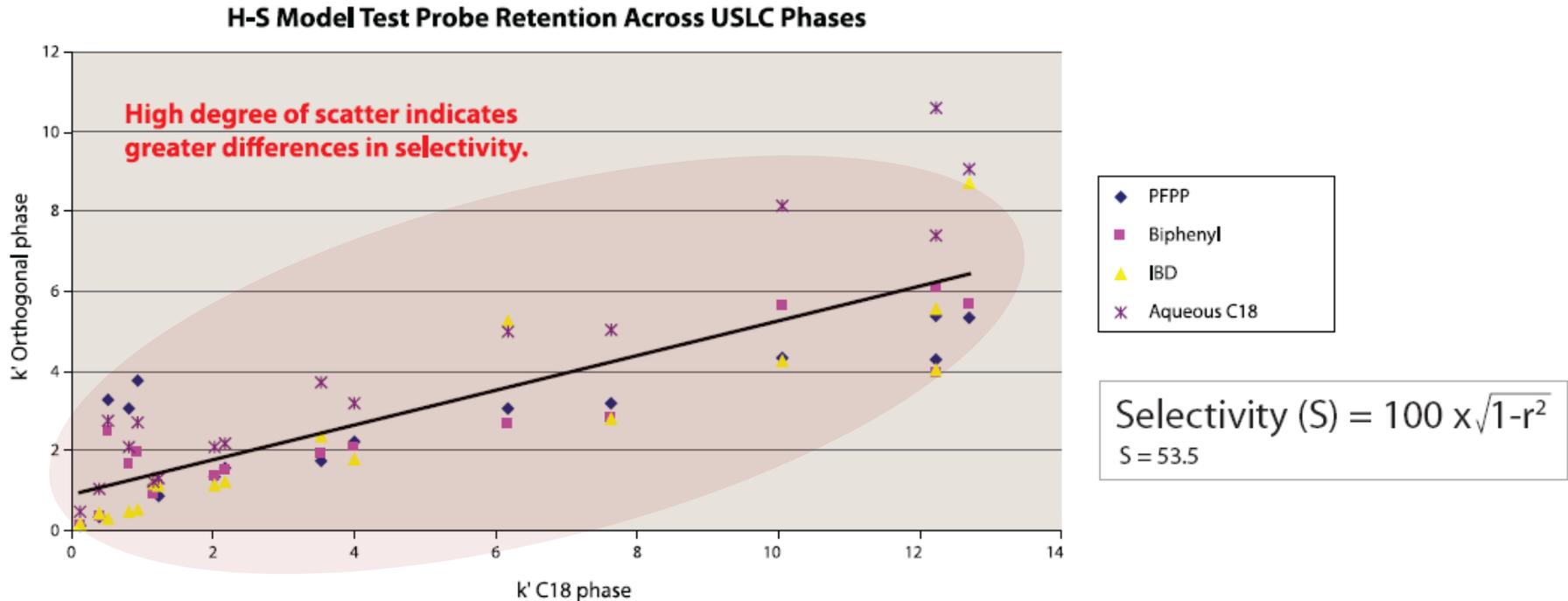
Selectivity on any Instrument Format

Figure 4: Restek USLC™ phases are available on several silica lines to accommodate any instrument platform or chromatographic application.

Column line (silica)	Pinnacle DB (Base deactivated, moderate retention silica for scalable UHPLC and HPLC analyses)	Ultra (Highest purity silica for traditional HPLC analyses)	Viva (Wide pore silica for biological separations using HPLC)
Particle diameters (µm)			
• UHPLC	1.9		
• HPLC		3 and 5	5
Stationary phases			
C18	●	●	●
C8	●	●	●
Aqueous C18	●	●	
Biphenyl	●	●	●
PFP Propyl	●	●	●
IBD	●	●	
Silica	●	●	●

The Value of Selectivity

Correlation of Orthogonal Phase Selectivity Relative to C18

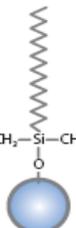
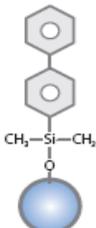
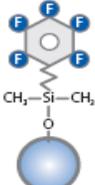


[2] U.D. Neue, J.E. O’Gara, A. Mendez, J. Chromatogr. A 1127 (2006) 161.

Restek currently has the largest range of selectivity in HPLC and UHPLC

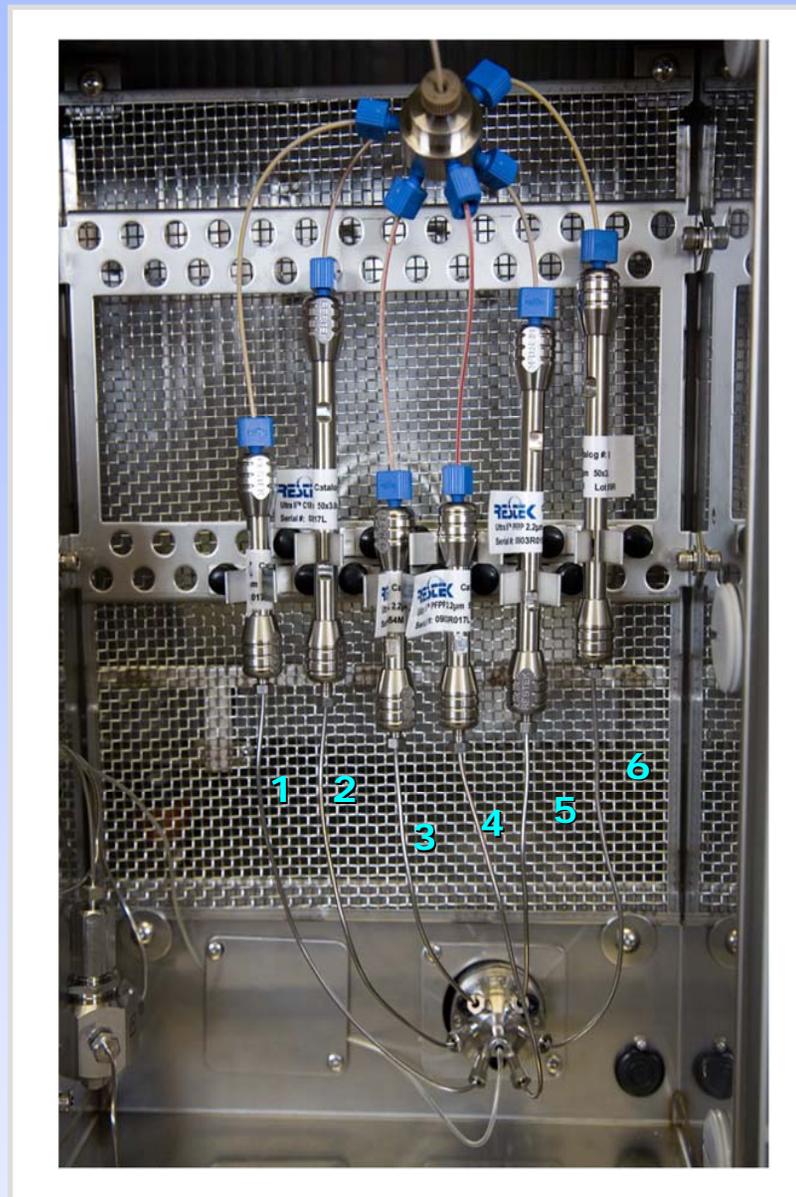
USLC Phases have the highest range of selectivity for RPC

Figure 1: Restek columns offer the widest range of unique and effective column chemistries to aid the chromatographer in fast and easy method development.

Restek phase (column class)	Aqueous C18 (alkyl)	IBD (polar embedded)	Biphenyl (phenyl)	PPF Propyl (fluorophenyl)
	 <p>Aqueous C18</p>	 <p>C18</p>	 <p>Biphenyl</p>	 <p>PPF Propyl</p>
Ligand type	Proprietary polar modified and functionally bonded C18	Proprietary polar functional embedded alkyl	Unique Biphenyl	Proprietary end-capped pentafluorophenyl propyl
Characteristics and uses	<ul style="list-style-type: none"> • C18 phase for balanced retention of multiple solute types. • Compatible with up to 100% aqueous mobile phases. 	<ul style="list-style-type: none"> • Enhanced retention of polar acids. • Moderate retention of both acidic and basic solutes. 	<ul style="list-style-type: none"> • Increased retention of aromatic, unsaturated, conjugated solutes, or solutes containing an electron withdrawing ring substituent. • Enhanced retention and selectivity when used with methanolic mobile phases. 	<ul style="list-style-type: none"> • Increased retention of protonated bases and solutes containing aromatic moieties.

Great for Column Switching

- Automated Column Selection
- Attach multiple mobile and stationary phases to system and systematically scout gradients
- Fast and effective method development
- Most Effective with Widest Variety of Stationary Phases



Courtesy of Shimadzu

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Biphenyl Advantage

Biphenyl can provide improved selectivity and retention over competitive and traditional phenyls as well as phenyl hexyls and diphenyls

★ **Biphenyl columns are more retentive for drug compounds than conventional phenyl and C18 phases, and are an excellent choice for LC/MS or the analysis of complex biological matrices.** ★

★ **The versatility of a Biphenyl column makes it an invaluable tool for the practicing method developer and a great addition to column screening systems.** ★

Biphenyl has been, and continues to be, very successful in the domestic market

The Evolution of Resolution

Figure 1 The Biphenyl phase provides higher retention of both hydrophobic and hydrophilic aromatic compounds and is capable of stronger pi-pi interactions than other phenyl phases.



BIPHENYL

- Incorporates aryl linker to the surface silica
- Highest hydrophobic retention of all phenyl phases
- Highest aromatic selectivity of all phenyl phases



PHENYL HEXYL

- Incorporates hexyl linker to the surface silica
- Increased hydrophobic retention
- Increased aromatic selectivity



DIPHENYL

- High density phenyl stationary phase
- Higher hydrophobic retention than conventional phenyl phases
- Capable of more aromatic selectivity than conventional phenyl phases



PHENYL PROPYL

- Conventional phenyl stationary phase
- Weak to moderate hydrophobic retention
- Capable of aromatic selectivity



ODS (OCTADECYLSILANE) OR C18

- Most popular reversed phase column
- Strong hydrophobic retention (dispersive interactions)
- Not selective towards aromatic compounds

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Viva - Wide-Pore Silica for Bio Pharma



Viva Wide Pore HPLC Columns
Spectacular performance for peptides, proteins, or other large molecules.

[Find out more](#)

For the separation of compounds of MW greater than approximately 2000Da – Proteins and Bio Pharma

- Restek manufactured and tightly controlled for effective chromatography and reproducibility - **Accurate and precise pore volume**
- Wide Variety of stationary phases available
 - C4, C8, C18, Silica, **Biphenyl, PFP Propyl, IBD**

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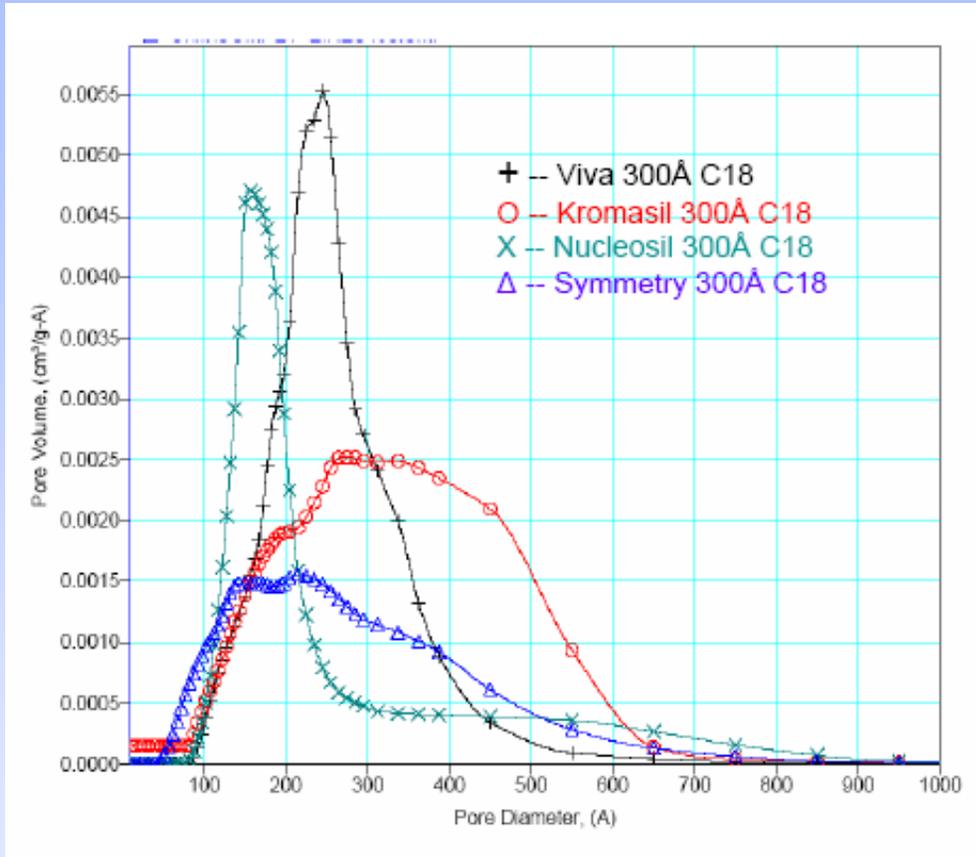
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BJH Desorption dV/dD Pore Volume



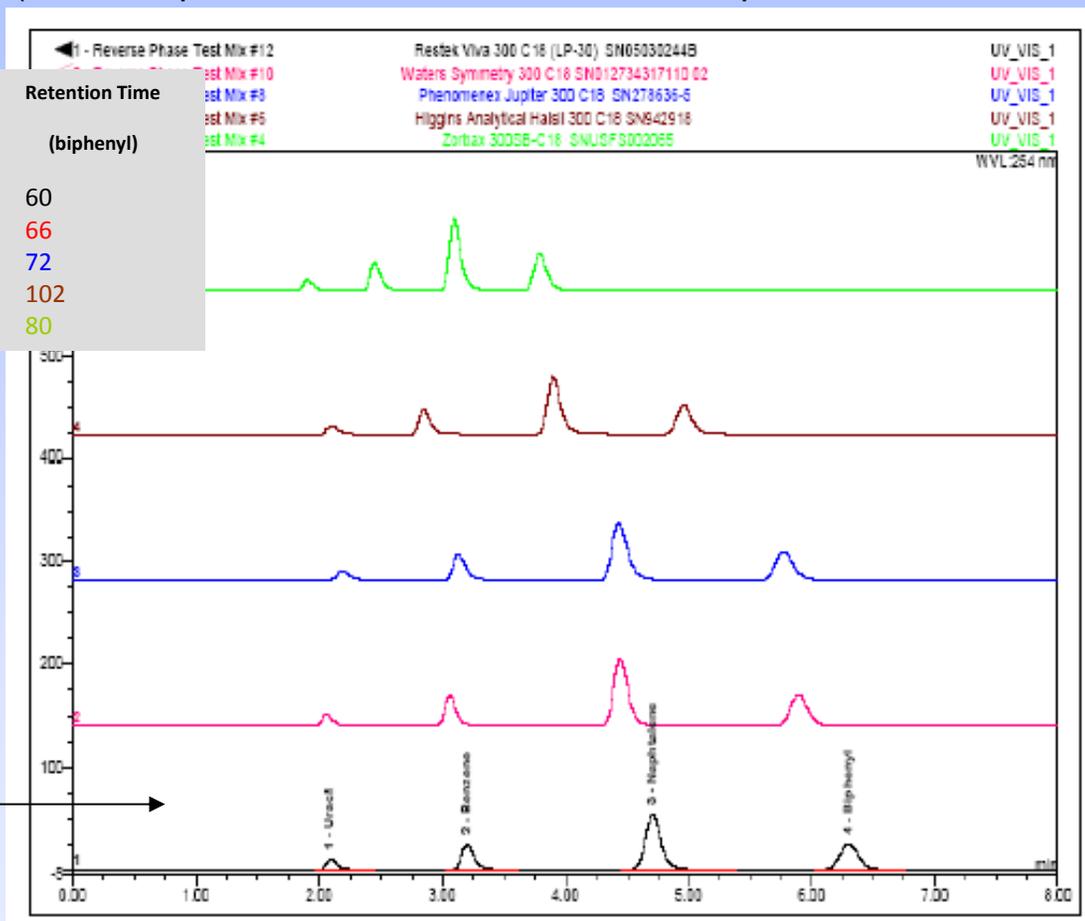
- Restek manufactured for control
- If they wont fit, they wont separate
 - Wide distribution means molecules may not fit

Only Viva™ silica has a narrow distribution with the majority of pores falling within the 250–350Å range.

Viva Competitive Comparison

Viva™ wide pore C18 columns provide the best overall performance among five tested columns (reversed phase test mix; 150 x 2.1mm C18 phase columns, 5µm particles).

	Pressure (bar)	Efficiency (plates/meter)	Asymmetry (biphenyl)	Retention Time (biphenyl)
Viva™ 300 C18	52,146	1.16	6.30	60
Waters C18	57,326	1.30	5.89	66
Phenomenex C18	49,720	1.46	5.77	72
Higgins C18	51,813	1.46	4.96	102
Zorbax C18	41,666	1.49	3.79	80



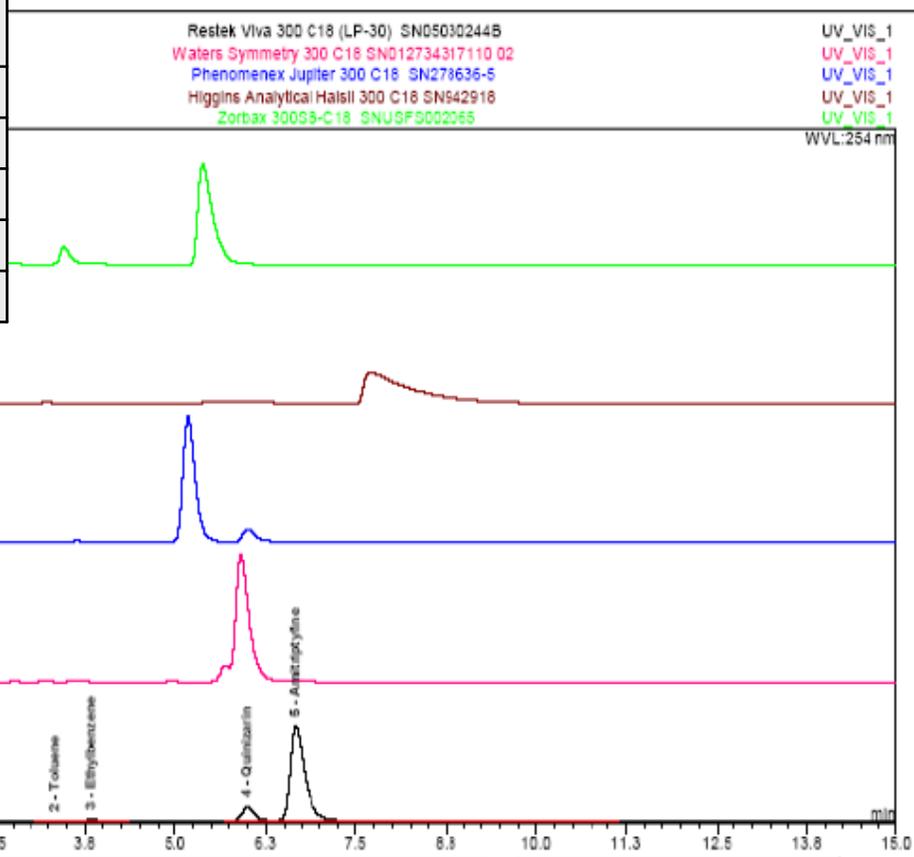
9514562) Column: Viva™ C18, 150 x 2.1mm, 5µm (cat.#
 Mobile Phase: water:methanol, 25:75
 Flow Rate: 0.2mL/min.
 Detector: UV @ 254nm
 Sample: 10µL Reversed Phase Test
 Mix (cat.# 35005)

Widest spread, most symmetrical peaks →

Viva Competitive Comparison

Viva™ wide pore C18 columns provide low silanol activity and low metals activity

	Silanol Activity	Metal Activity	Embedded Polar Functionality
Viva 300 C18	Low	Low	No
Waters 300 C18	Low	Low	No
Phenomenex 300 C18	Low	Low	Yes
Higgins 300 C18	High	High	No
Zorbax 300 C18	Low	Low	No



Column: Viva™ C18, 150 x 2.1mm, 5µm
(cat.# 9514562)
Mobile Phase: A=20% 5mmol $K_xH_yPO_4$, pH = 7.0
B=80% Methanol
Flow Rate: 0.2ml/min.
Detector: UV, 254nm
Injection: 1ml SRM870 test mix

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Viva Competitive Comparison

Analysis of a four-protein test mix shows the superior performance of the Viva™ C18 column

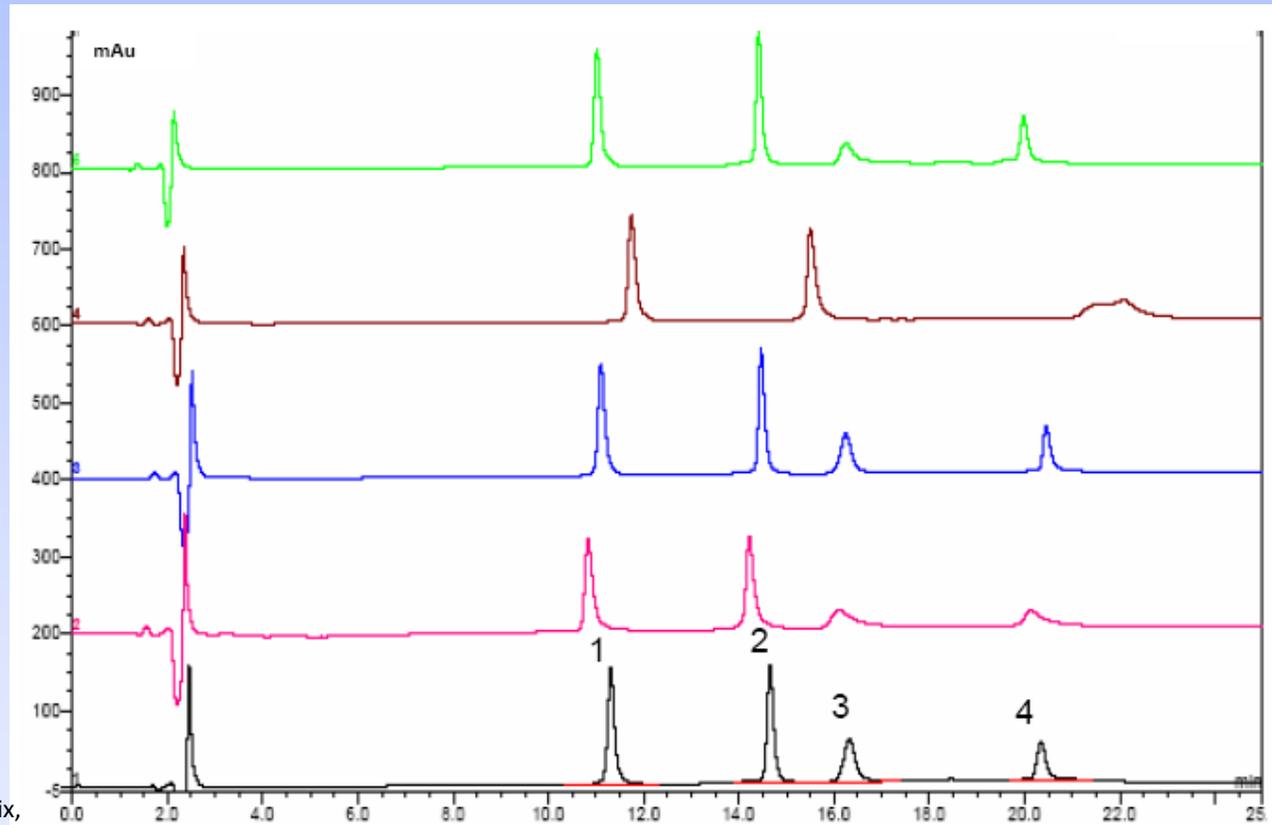
Waters Symmetry 300 C18,
150mm x 2.1mm, 5µm

Phenomenex Jupiter 300 C18,
150mm x 2.1mm, 5µm

Higgins Analytical Haisil C18,
150mm x 2.1mm, 5µm

Zorbax 300SB-C18,
150mm x 2.1mm, 5µm

Column: Viva™ C18, 150 x 2.1mm, 5µm
(cat.# 9514562)
Mobile Phase: A: 0.1% TFA in water, (pH 2.0)
B: 0.1% TFA in acetonitrile
20% B to 70% B in 30 min.
Flow Rate: 0.2mL/min.
Detector: UV @ 214nm
Injection: Four Protein Standard Test Mix,
Sigma Aldrich #H2899



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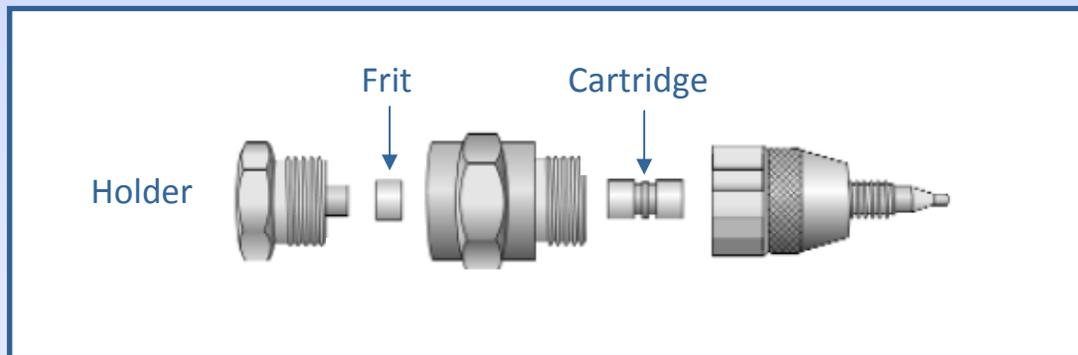
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Guard Columns - a necessity

- Usually same packing material as analytical column
- Inexpensive
- Sample compatibility
- Low sample dispersion
- Adequate capacity
- Minimal loss of efficiency



Guard Column Options



Trident Direct Guard Cartridge System



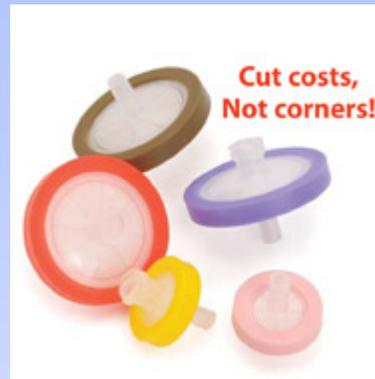
Restek's Exclusive Trident Integral System



Trident HPLC In-Line Guard Cartridge Holders

Other LC interesting products

Individual product line promotions that can be easily applied for cross-selling opportunities



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GC in Pharmaceutical Market

- Organic volatile impurities
 - Widely used to verify contaminants in solvents used to make pharmaceutical products
- Restek developed new column phase
 - Rxi-624Sil MS
- Column selectivity has been carefully tuned to give the best performance for analysis of solvents



3-IN-1 TECHNOLOGY

Highest Inertness • Lowest Bleed • Exceptional Reproducibility

- Literature

- Promotional Brochures
 - Rxi Flyer – GNFL1173
 - Rxi-5Sil MS – GNFL1061
 - Rxi-624Sil MS – PHFL1245
 - USP <467> - PHFL1018A
- Application Notes and Technical Articles
 - Outsourcing Solvent Methods – PHTS1262
 - USP <467> - On-line
 - How Column Inertness Improves...PHAN1259
 - PGI Analysis – On-Line

http://www.restek.com/aoi_pharm_main.asp

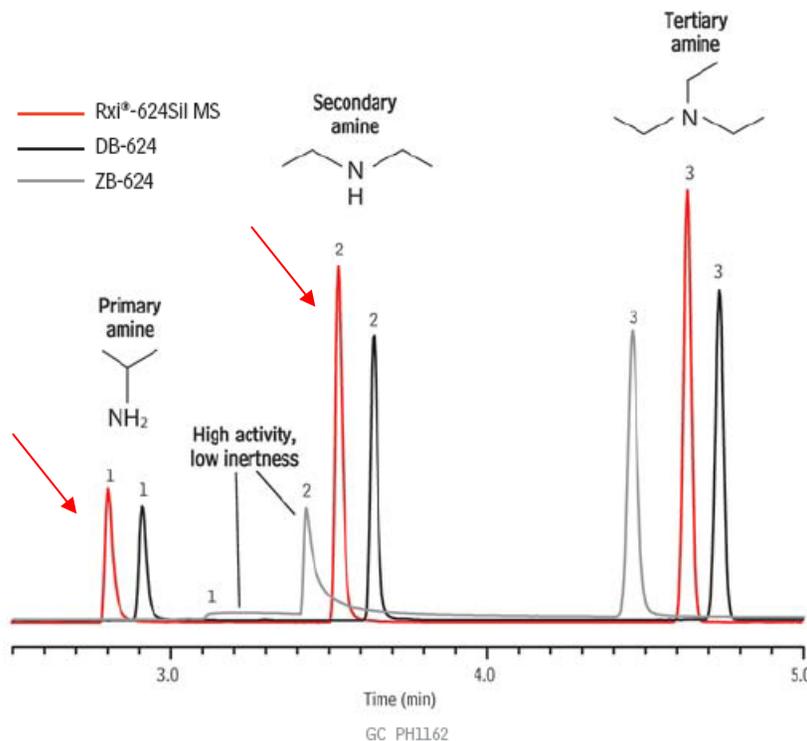
- Webinars

Practical Method Development for gas Chromatography

Balanced Inertness

Balanced Inertness Gives Higher Data Quality— Excellent Peak Symmetry and Reproducibility for Active Compounds

Figure 2 Innovative Rxi® deactivation technology provides excellent peak symmetry at 5 ng on-column for primary, secondary, and tertiary amines, which is not possible on competitive columns.



**Highly inert Rxi®-624Sil MS columns
give excellent peak symmetry.**

Peaks	Conc. ($\mu\text{g/mL}$)
1. Isopropylamine	100
2. Diethylamine	100
3. Triethylamine	100

Column	30 m, 0.32 mm ID, 1.8 μm (cat.# 13870)
Sample	Isopropylamine
Diluent:	DMSO
Conc.:	100 $\mu\text{g/mL}$
Injection	
Inj. Vol.:	1 μL split (split ratio 20:1)
Liner:	5mm Single Gooseneck with Wool (cat.# 22973-200.1)
Inj. Temp.:	250 $^{\circ}\text{C}$
Oven	
Oven Temp:	50 $^{\circ}\text{C}$ (hold 1 min.) to 200 $^{\circ}\text{C}$ at 20 $^{\circ}\text{C}/\text{min.}$ (hold 5 min.)
Carrier Gas	He, constant flow
Linear Velocity:	37 cm/sec.
Detector	FID @ 250 $^{\circ}\text{C}$
Instrument	Agilent/HP6890 GC

Balanced Inertness -

Balanced Inertness Gives Higher Data Quality— Excellent Peak Symmetry and Reproducibility for Active Compounds

Figure 3 Primary amines, such as isopropylamine, can be more accurately integrated on an Rxi[®]-624Sil MS column, lowering levels of quantification (LOQs) and increasing method accuracy.

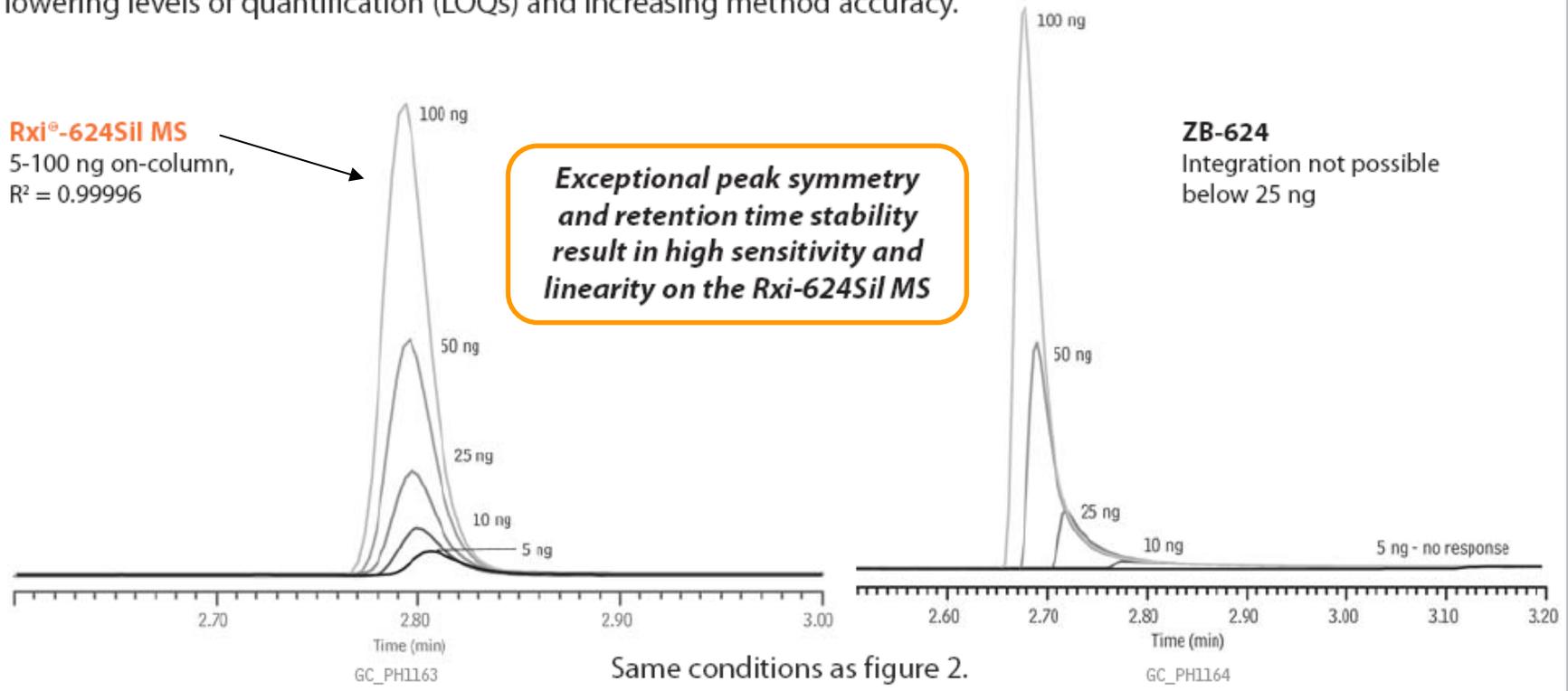
Rxi[®]-624Sil MS

5-100 ng on-column,
 $R^2 = 0.99996$

*Exceptional peak symmetry
and retention time stability
result in high sensitivity and
linearity on the Rxi-624Sil MS*

ZB-624

Integration not possible
below 25 ng



Highest Thermal Stability of its Class

High Thermal Stability and Low Bleed for GC/MS Compatibility

Table I The Rxi®-624Sil MS column has the highest thermal stability of any 624 column.

Column	Manufacturer	Highest Temperature Limit (Isothermal)
Rxi®-624Sil MS	Restek	320 °C
VF-624ms	Varian	300 °C
DB-624	Agilent J&W	260 °C
ZB-624	Phenomenex	260 °C

Data obtained from company website or literature for a 30 m x 0.25 mm x 1.4 µm df column.



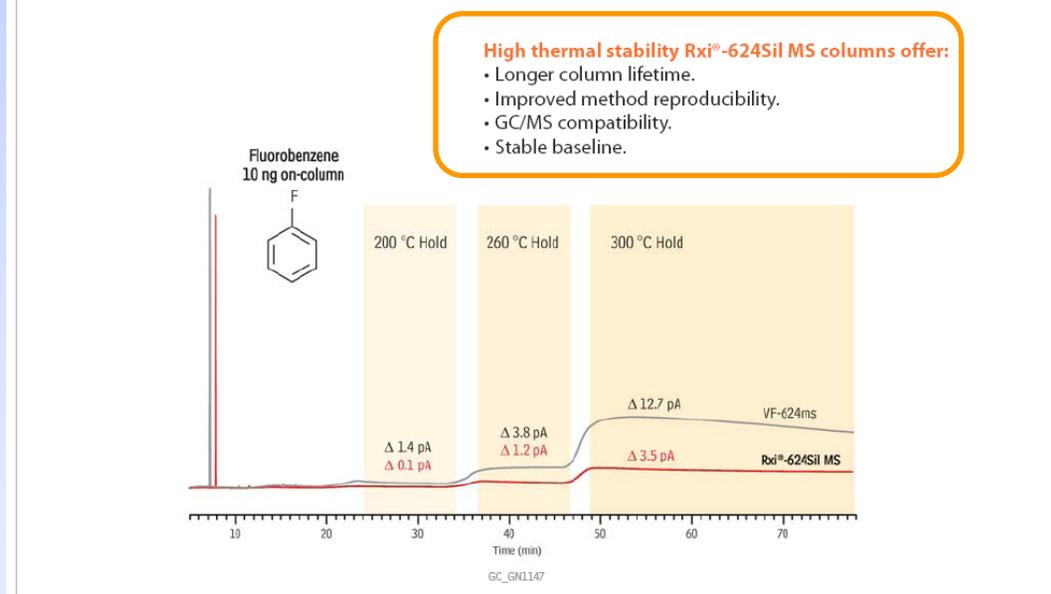
- Low Bleed, high thermal stability polymer

- MS compatibility – no need to change columns when converting FID to MS

- Stable baselines for consistent results

- Longer column lifetimes

Figure 5 The Rxi®-624Sil MS column has the lowest bleed of any column in its class, providing true GC/MS capability.



Rxi Essentials for Pharma Use



Pharmaceutical

Go To...the Right Column First

NEW! Rxi®-624Sil MS

The **Go To** GC Column for Fast, Effective Volatile Impurities Method Development

Go To... the right column first

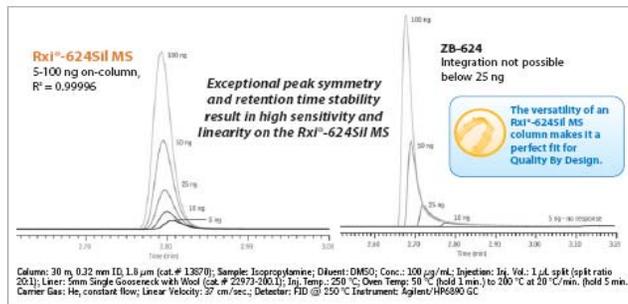
For better retention of polar analytes and improved accuracy, peak shape, and response for active compounds.

Go To... mass spec directly

With the lowest bleed 624 column available; stable up to 320 °C, for easy transfer of methods to GC/MS.

Go To... the next batch faster

With the best-in-class G43 for USP methods.



Rxi®-624Sil MS Columns (fused silica)

- Low bleed, high thermal stability column—maximum temperatures up to 320°C.
- Inert—excellent peak shape for a wide range of compounds, including acidic and basic compounds.
- Selective—highly selective for residual solvents, great choice for USP<467>.
- Manufactured for column-to-column reproducibility—well-suited for validated methods.

(Inid polarity Crossbond® silylene phase; equivalent to 6% cyanopropylphenyl/94% dimethyl polysiloxane)

ID	d _f (µm)	Temp. Limits	20-Meter	30-Meter	60-Meter
0.18mm	1.00	-20 to 300/320°C	13865	\$405	
0.25mm	1.40	-20 to 300/320°C		13868	\$500
0.32mm	1.80	-20 to 300/320°C		13870	\$540
0.53mm	3.00	-20 to 280/300°C		13871	\$615



Not all "624s" are Equivalent

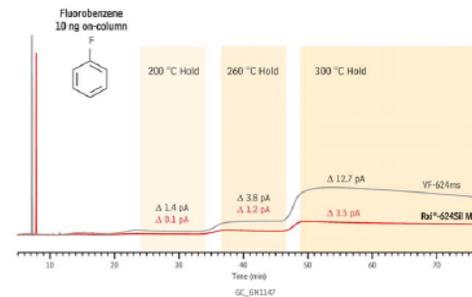
High thermal stability Rxi®-624Sil MS columns offer:

- Longer column lifetime.
- Improved method reproducibility.
- GC/MS compatibility.
- Stable baseline.

Column	Manufacturer	Highest Temperature Limit (Isotherm)
Rxi®-624Sil MS	Restek	320 °C
VF-624ms	Varian	300 °C
DB-624	Agilent J&W	260 °C
ZB-624	Phenomenex	260 °C



Ideal for use with FID and MS detectors.



Couple the right column with the right liner. Visit www.restek.com/liners for a complete selection.



Custom Residual Solvent Mixes

A perfect match for validated residual solvent methods

Save time and money with mixes prepared to your specific solvent set and concentrations. The more you buy the less you pay per ampul!

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www.restek.com/customusp



Make the Switch to Rxi® columns!

Experience what Rxi® did for many others

- Lower detection limits
- Better peak shape
- Accurate results

www.restek.com/rxi

Rxi Updated Brochure

Lit. Cat.# PHFL1018A

Residual Solvent Analysis

Implementing USP <467>

- Satisfy USP <467> requirements—detailed procedures inside.
- Improve system suitability pass rates with an optimized system.
- Easy technical tips ensure successful implementation.

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Updated brochure for the USP <467>

This is the technical flyer meant to assist customers in implementing the method

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USP <467> Standards



USP-equivalent Standards

Residual Solvents - Class 1

benzene	10mg/mL	1,1-dichloroethene	40
carbon tetrachloride	20	1,1,1-trichloroethane	50
1,2-dichloroethane	25		

In dimethyl sulfoxide, 1mL/ampul
cat. # 36279 (ea.) \$30

Residual Solvents Class 2 - Mix A

acetonitrile	2.05mg/mL	methylcyclohexane	5.90
chlorobenzene	1.80	methylene chloride	3.00
cyclohexane	19.40	tetrahydrofuran	3.45
<i>cis</i> -1,2-dichloroethene	4.70	toluene	4.45
<i>trans</i> -1,2-dichloroethene	4.70	<i>m</i> -xylene	6.51
1,4-dioxane	1.90	<i>o</i> -xylene	0.98
ethylbenzene	1.84	<i>p</i> -xylene	1.52
methanol	15.00		

In dimethyl sulfoxide, 1mL/ampul
cat. # 36271 (ea.) \$30

Residual Solvents Class 2 - Mix B

chloroform	60µg/mL	nitromethane	50
1,2-dimethoxyethane	100	pyridine	200
<i>n</i> -hexane (C6)	290	tetralin	100
2-hexanone	50	trichloroethene	80

In dimethyl sulfoxide, 1mL/ampul
cat. # 36280 (ea.) \$30

Residual Solvents Class 2 - Mix C

2-ethoxyethanol	800µg/mL	2-methoxyethanol (methyl	
ethylene glycol	3,100	Cellulosolve)	250
formamide	1,100	N-methylpyrrolidone	2,650
N,N-dimethylacetamide	5,450	sulfolane	800
N,N-dimethylformamide	4,400		

In dimethyl sulfoxide, 1mL/ampul
cat. # 36273 (ea.) \$30

USP <467> Singles

Volume is 1mL/ampul.

Compound	Solvent	Conc.	cat.# (ea.)	price
acetonitrile	DMSO	2.05mg/mL	36281	\$26
benzene	DMSO	10mg/mL	36282	\$26
carbon tetrachloride	DMSO	20mg/mL	36283	\$26
chlorobenzene	DMSO	1.8mg/mL	36284	\$26
chloroform	DMSO	0.3mg/mL	36285	\$26
cyclohexane	DMSO	19.4mg/mL	36286	\$26
1,1-dichloroethene	DMSO	40mg/mL	36287	\$26
1,2-dichloroethane	DMSO	25mg/mL	36288	\$26
<i>cis</i> -1,2-dichloroethene	DMSO	4.67mg/mL	36289	\$26
<i>trans</i> -1,2-dichloroethene	DMSO	4.67mg/mL	36290	\$26
1,2-dimethoxyethane	DMSO	0.5mg/mL	36291	\$26
N,N-dimethylacetamide	DMSO	5.45mg/mL	36292	\$26
N,N-dimethylformamide	DMSO	4.4mg/mL	36293	\$26
1,4-dioxane	DMSO	1.9mg/mL	36294	\$26
2-ethoxyethanol	DMSO	0.8mg/mL	36295	\$26
ethylbenzene	DMSO	1.84mg/mL	36296	\$26
ethylene glycol	DMSO	3.1mg/mL	36297	\$26
formamide	DMSO	1.1mg/mL	36298	\$26
hexane	DMSO	1.45mg/mL	36299	\$26
methanol	DMSO	15mg/mL	36401	\$26
2-methoxyethanol	DMSO	0.25mg/mL	36402	\$26
methylbutylketone	DMSO	0.25mg/mL	36400	\$26
methylcyclohexane	DMSO	5.9mg/mL	36403	\$26
methylene chloride (dichloromethane)	DMSO	3mg/mL	36404	\$26
N-methylpyrrolidone	DMSO	2.65mg/mL	36405	\$26
nitromethane	DMSO	0.25mg/mL	36406	\$26
pyridine	DMSO	1mg/mL	36407	\$26
sulfolane	DMSO	0.8mg/mL	36413	\$26
tetrahydrofuran (THF)	DMSO	3.6mg/mL	36408	\$26
tetralin	DMSO	0.5mg/mL	36409	\$26
toluene	DMSO	4.45mg/mL	36410	\$26
1,1,1-trichloroethane	DMSO	50mg/mL	36411	\$26
trichloroethene	DMSO	0.4mg/mL	36412	\$26
<i>m</i> -xylene	DMSO	6.51mg/mL	36414	\$26
<i>o</i> -xylene	DMSO	0.97mg/mL	36415	\$26
<i>p</i> -xylene	DMSO	1.52mg/mL	36416	\$26

DMSO=dimethyl sulfoxide

USP < 467 > Standards



Custom Standards

Restek is your #1 source for custom reference standards!

- **Save time!** Let us prepare your standards, blended precisely to your specifications.
- **Save money!** Custom mixes for your processes; don't pay for solvents you don't need.
- **Great value!** Volume discounts on fully-qualified standards.

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BIG SAVINGS

Custom Residual Solvents Mixes

- **Save time!** Let us prepare your standards, blended precisely to your specifications.
- **Save money!** Custom mixes for your processes; don't pay for solvents you don't need.
- **Great value!** Volume discounts on fully-qualified standards.

Buy More, Save More!
 Restek Custom Residual Solvent Mixes are a great way to save money and time in the laboratory. You can buy exactly what you need—mixed to your specifications—and not pay for components you don't need.

Savings vary based on the size and how much you purchase. Here's an example custom order and the associated savings relative to list price.

Example Order
 This customer saved 94% off list price!

Solvent	Cat #	Conc. (vol/vol)
Acetone	47-04-1	0.01
Acetonitrile	75-01-8	0.01
2-Butanone (MEK)	78-09-3	0.01
Cyclohexane	109-62-7	0.01
Ethanol	44-07-3	0.01
Ethyl acetate	141-78-4	0.01
Methanol	65-56-1	0.01
n-Butyl-2-pyrrolidone (MBE)	106-10-1	0.01
Methyl tert-butyl ether (MTBE)	1634-04-4	0.01
Methylene chloride	75-09-2	0.01
2-Methoxyethoxyethane	36-47-9	0.01
2-Propanol	67-63-0	0.01
Tetrahydrofuran	309-29-3	0.01
Toluene	108-88-3	0.01

Number of Ampoules	Price/Ampou	Year Save
5	\$170	49%
10	\$110	71%
25	\$40	90%
100	\$11	94%
500	\$4	94%

Buy more, SAVE MORE!

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Custom Solvent Mix Order Form

Name: _____ Title: _____
 Company: _____
 Address: _____
 Phone: _____ Fax: _____
 E-mail: _____

We distribute: Anhydrous (99%)
 Reagent grade: _____
 Proprietary: _____
 Preparation info: _____

Solvent	Cat #	Concentration (vol/vol)	Solvent	Cat #	Concentration (vol/vol)
Acetone	47-04-1	0.01	Acetonitrile	75-01-8	0.01
Acetonitrile	75-01-8	0.01	2-Butanone (MEK)	78-09-3	0.01
2-Butanone (MEK)	78-09-3	0.01	Cyclohexane	109-62-7	0.01
Cyclohexane	109-62-7	0.01	Ethanol	44-07-3	0.01
Ethanol	44-07-3	0.01	Ethyl acetate	141-78-4	0.01
Ethyl acetate	141-78-4	0.01	Methanol	65-56-1	0.01
Methanol	65-56-1	0.01	n-Butyl-2-pyrrolidone (MBE)	106-10-1	0.01
n-Butyl-2-pyrrolidone (MBE)	106-10-1	0.01	Methyl tert-butyl ether (MTBE)	1634-04-4	0.01
Methyl tert-butyl ether (MTBE)	1634-04-4	0.01	Methylene chloride	75-09-2	0.01
Methylene chloride	75-09-2	0.01	2-Methoxyethoxyethane	36-47-9	0.01
2-Methoxyethoxyethane	36-47-9	0.01	2-Propanol	67-63-0	0.01
2-Propanol	67-63-0	0.01	Tetrahydrofuran	309-29-3	0.01
Tetrahydrofuran	309-29-3	0.01	Toluene	108-88-3	0.01
Toluene	108-88-3	0.01			

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GC Column Mix for Pharma Method Development

Rxi-5Sil MS



Rxi-17Sil MS



Rxi-624Sil MS



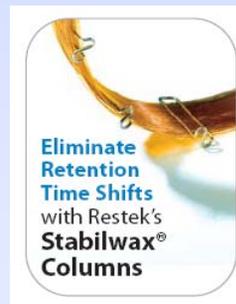
Stabilwax



Phase:	Non-polar	—————→		Polar
Thermal Stability:	High (360)	350	320	Low (260)
Inst. Compat.	GC/MS			GC/FID only
Deactivation:	Balanced Amine (follow with same deactivation for liners)			DA vs DB option

Four GC column phases recommended for organic volatile impurities

- Wide variation in selectivity
- Highly thermally stable columns
- Very inert
- Reproducible from column to column



Summary

- HPLC
 - USLC
 - Ultra Selective Liquid Chromatography
 - Focus on:
 - Ultra (Type B silica, more inert)
 - 3um and 5um particles
 - Pinnacle DB (Type A silica)
 - 1.9um particles
 - Viva (large molecules, Proteins and Bio Pharma)
- GC
 - Organic volatile impurities
 - Rxi-624Sil MS
 - Best selectivity choices
 - Rxi-5Sil MS, Rxi-17Sil MS, Rxi-624Sil MS, Stabilwax