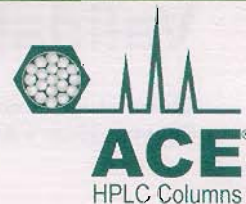


Batch Validation



Silica Type: ACE 5 C8
Batch Number: DV06-1119

Material Characteristics

Underivatised Silica	Particle Size:	5µm
	Pore Size:	100Å
	Pore Volume:	1.0ml/g
	Surface Area:	300m ² /g
	Total Trace Metal Content:	<10ppm
Derivatised Silica	Carbon Content:	9.0%

Chromatographic Results

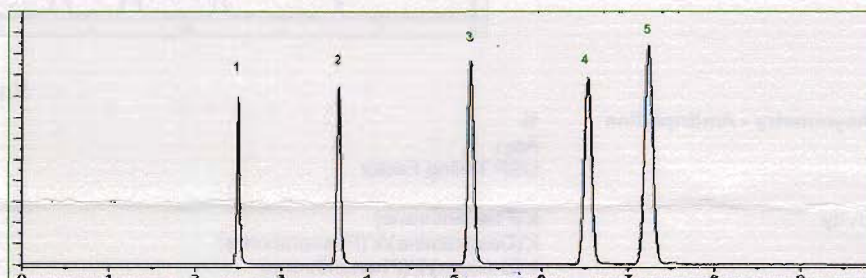
Validation – Neutral Molecules

Chromatographic Conditions

Column: 25cm x 4.6mm ID, Mobile Phase: 70:30 MeCN/H₂O, Flow Rate: 1.0ml/min, Temperature: 40°C

Peak Identification

1. Uracil
2. Dimethyl Phthalate
3. Toluene
4. Biphenyl
5. Phenanthrene



		Specification	Result
Efficiency - Dimethyl Phthalate	N _{0.5}	>110,000pl/m	117,800pl/m
Peak Asymmetry - Phenanthrene	%	>90	97
	As _{0.1}	0.95 - 1.15	1.05
	USP Tailing Factor	0.95 - 1.10	1.03
Selectivity	k' (Biphenyl)	1.45 - 1.57	1.54
	k' (Phenanthrene)	1.70 - 1.84	1.80

Please refer to care and use sheet for asymmetry and efficiency measurement information.

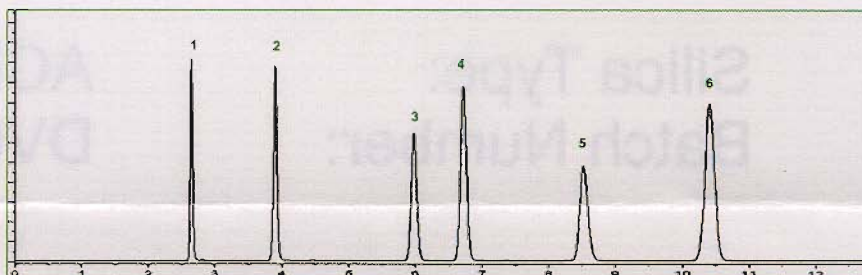
Validation - Acidic Molecules

Chromatographic Conditions

Column: 25cm x 4.6mm ID, Mobile Phase: 35:65 MeCN/0.1%TFA in H₂O, Flow Rate: 1.0ml/min, Temperature: 22°C

Peak Identification

1. Uracil
2. 4-Hydroxybenzoic acid
3. Acetylsalicylic acid
4. Benzoic acid
5. 2-Hydroxybenzoic acid
6. Ethyl paraben



Peak Asymmetry - Benzoic acid	%	Specification	Result
		>90	94
	AS _{0.1}	<1.50	1.29
	USP Tailing Factor	<1.30	1.19
Selectivity	k'(Ethyl paraben)	2.80 - 3.04	2.97
	k'(4-Hydroxybenzoic acid)/k'(Ethyl paraben)	0.159 - 0.165	0.161
	k'(Acetylsalicylic acid)/k'(Ethyl paraben)	0.421 - 0.439	0.427
	k'(Benzoic acid)/k'(Ethyl paraben)	0.515 - 0.537	0.520
	k'(2-Hydroxybenzoic acid)/k'(Ethyl paraben)	0.742 - 0.772	0.748

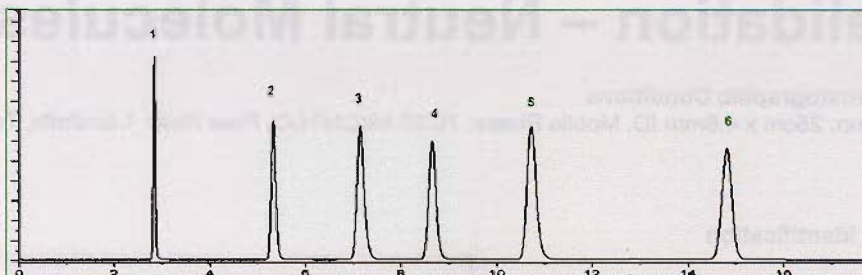
Validation - Basic Molecules

Chromatographic Conditions

Column: 25cm x 4.6mm ID, Mobile Phase: 70:30 MeOH/0.025M KH₂PO₄ (pH6.0), Flow Rate: 1.0ml/min, Temperature: 22°C

Peak Identification

1. Uracil
2. Desipramine
3. Doxepin
4. Imipramine
5. Amitriptyline
6. Phenanthrene



Peak Asymmetry - Amitriptyline	%	Specification	Result
		>90	93
	AS _{0.1}	<1.30	1.24
	USP Tailing Factor	<1.20	1.14
Selectivity	k'(Phenanthrene)	4.14 - 4.45	4.34
	k'(Desipramine)/k'(Phenanthrene)	0.199 - 0.215	0.208
	k'(Doxepin)/k'(Phenanthrene)	0.341 - 0.369	0.355
	k'(Imipramine)/k'(Phenanthrene)	0.460 - 0.498	0.476
	k'(Amitriptyline)/k'(Phenanthrene)	0.625 - 0.671	0.649

Material Approval: J. Williams
(Quality Control Manager)

Date: 14th November 2006