

Batch Validation



Silica Type: ACE 5 C18
Batch Number: V11-5080

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:	15.5%

Chromatographic Results

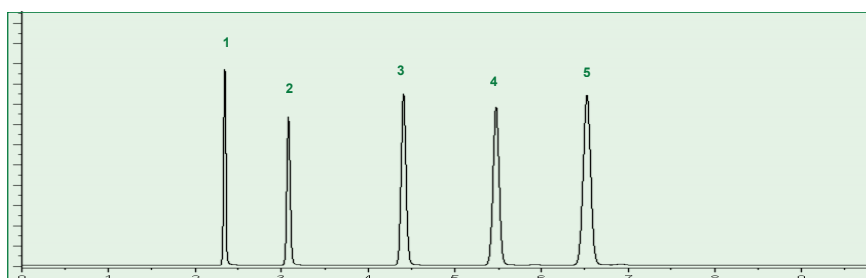
Validation – Neutral Molecules

Chromatographic Conditions

Column: 25cm x 4.6mm ID, Mobile Phase: 80:20 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	118,200pl/m
Peak Asymmetry - Phenanthrene	%	>90	97
	AS _{0.1}	0.95 - 1.15	1.04
	USP Tailing Factor	0.95 - 1.10	1.02
Selectivity	k' (Biphenyl)	1.30 - 1.40	1.36
	k' (Phenanthrene)	1.73 - 1.87	1.82

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

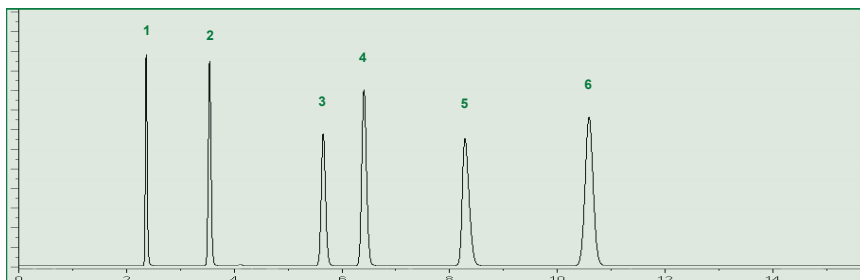
Validation - Acidic Molecules

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	95
As _{0.1}		<1.50	1.26
USP Tailing Factor		<1.30	1.14
Selectivity			
	k'(Ethyl paraben)	3.29 - 3.57	3.47
	k'(4-Hydroxybenzoic acid)/k'(Ethyl paraben)	0.139 - 0.145	0.142
	k'(Acetylsalicylic acid)/k'(Ethyl paraben)	0.390 - 0.406	0.396
	k'(Benzoic acid)/k'(Ethyl paraben)	0.480 - 0.500	0.487
	k'(2-Hydroxybenzoic acid)/k'(Ethyl paraben)	0.704 - 0.732	0.714

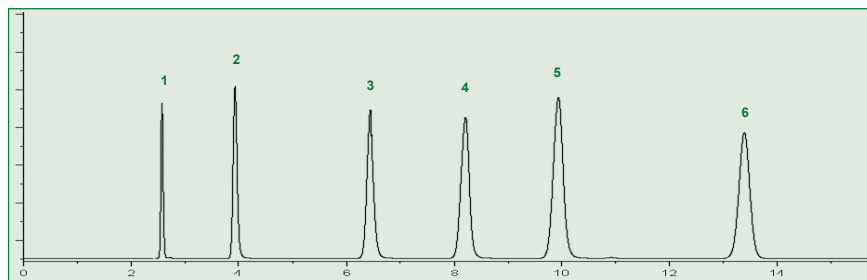
Validation - Basic Molecules

Chromatographic Conditions

Column: 25cm x 4.6mm ID, Mobile Phase: 80:20 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	95
As _{0.1}		<1.30	1.21
USP Tailing Factor		<1.20	1.13
Selectivity			
	k'(Phenanthrene)	4.08 - 4.42	4.27
	k'(Desipramine)/k'(Phenanthrene)	0.120 - 0.130	0.124
	k'(Doxepin)/k'(Phenanthrene)	0.340 - 0.368	0.354
	k'(Imipramine)/k'(Phenanthrene)	0.496 - 0.538	0.517
	k'(Amitriptyline)/k'(Phenanthrene)	0.654 - 0.708	0.674

Material Approval:

J Williams

(Quality Control Manager)

Date:

6th April 2011