

APPLICATION

Doxylamine Impurity Profile Using a Kinetex® EVO C18 Core-Shell LC Column

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Overview

The manufacturing of a pharmaceutical product results in the accumulation of impurities from a variety of sources. Pharmaceutical regulatory agencies require that an impurity profiling testing method is utilized to ensure that the amount of impurities is below an allowable limit. As demonstrated below, a high performance core-shell Kinetex EVO C18 column obtains narrow peak shape and extremely useful resolution for a doxylamine formulation impurity profile. Unlike traditional fully porous and core-shell products, the pH 1-12 stability of the EVO C18 material allows this method to utilize a high pH mobile phase that aids in retention and separation. More so, the sharp, narrow peak shape means that more accurate quantification and therefore more reliable data is obtained.

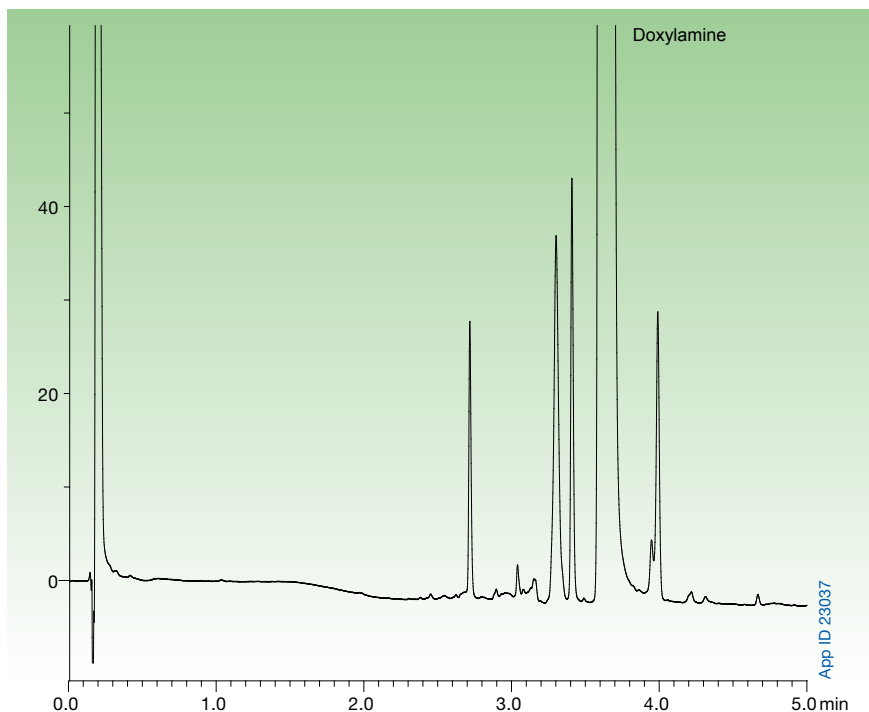
LC/UV Conditions

Column: Kinetex 2.6µm EVO C18
Dimensions: 50 x 2.1 mm
Part No.: 00B-4725-AN
Mobile Phase: A: 20 mM Ammonium bicarbonate (pH 10)
 B: Acetonitrile
Gradient:

Time (min)	% B
0	5
5	95

Flow Rate: 0.7 mL/min
Temperature: Ambient
Detection: UV @ 254 nm
Sample: Impurity profile of Doxylamine
Concentration: 25 mg/mL API in DMSO

Find more information on Kinetex core-shell HPLC and UHPLC columns at:
www.phenomenex.com/kinetex



APPLICATION

Ordering Information

Kinetex[®] EVO C18 Core-Shell LC Columns

5 µm Minibore Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]
30 x 2.1	50 x 2.1	100 x 2.1	150 x 2.1	3/pk
00A-4633-AN	00B-4633-AN	00D-4633-AN	00F-4633-AN	AJO-9298
for 2.1 mm ID				

5 µm MidBore [™] Columns (mm)			SecurityGuard [™] ULTRA Cartridges [†]
50 x 3.0	100 x 3.0	150 x 3.0	3/pk
00B-4633-YO	00D-4633-YO	00F-4633-YO	AJO-9297
for 3.0 mm ID			

5 µm Analytical Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]
50 x 4.6	100 x 4.6	150 x 4.6	250 x 4.6	3/pk
00B-4633-E0	00D-4633-E0	00F-4633-E0	00G-4633-E0	AJO-9296
for 4.6 mm ID				

2.6 µm Minibore Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]
30 x 2.1	50 x 2.1	100 x 2.1	150 x 2.1	3/pk
00A-4725-AN	00B-4725-AN	00D-4725-AN	00F-4725-AN	AJO-9298
for 2.1 mm ID				

2.6 µm MidBore [™] Columns (mm)			SecurityGuard [™] ULTRA Cartridges [†]
50 x 3.0	100 x 3.0	150 x 3.0	3/pk
00B-4725-YO	00D-4725-YO	00F-4725-YO	AJO-9297
for 3.0 mm ID			

2.6 µm Analytical Columns (mm)				SecurityGuard [™] ULTRA Cartridges [†]
50 x 4.6	100 x 4.6	150 x 4.6	3/pk	
00B-4725-E0	00D-4725-E0	00F-4725-E0	AJO-9296	
for 4.6 mm ID				

1.7 µm Minibore Columns (mm)			SecurityGuard [™] ULTRA Cartridges [†]	
50 x 2.1	100 x 2.1	150 x 2.1	3/pk	
00B-4726-AN	00D-4726-AN	00F-4726-AN	AJO-9298	
for 2.1 mm ID				

[†] SecurityGuard ULTRA Cartridges require holder, Part No.: AJO-9000

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Kinetex EVO is patented by Phenomenex. U.S. Patent Nos. 7,563,367 and 8,658,038 and foreign counterparts.

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