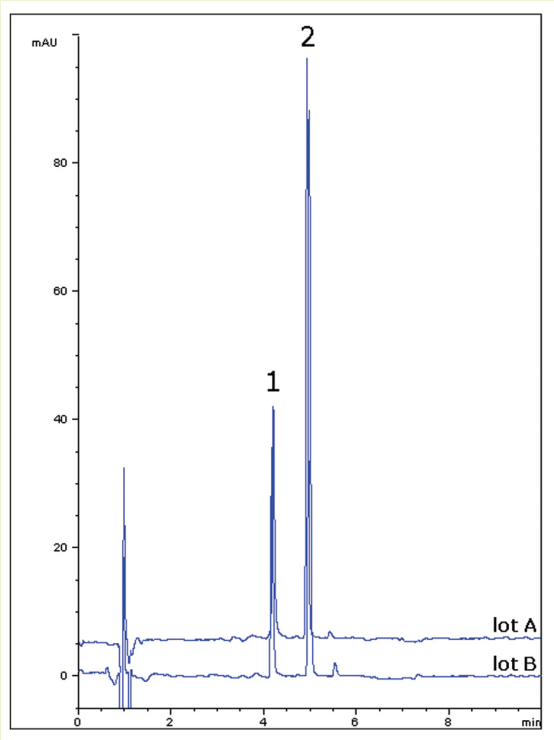
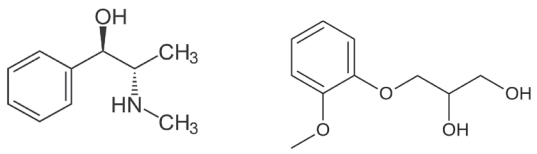
Primatene® Tablet

Separation of guaifenesin and ephedrine in a real formulation





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Note: Primatene tablet containing 12.5mg ephedrine HCl and 200mg guaifenesin was ground and added to a 25mL volumetric flask. A portion of 50/50 solvent A/solvent B diluent was added and the flask was sonicated 10 min. It was then diluted to mark and mixed. A portion was filtered with a 0.45µm nylon syringe filter (MicroSolv Tech Corp.) and diluted 1:10.

Method Conditions

Column: **Cogent Bidentate C18™**, 4µm, 100Å

Catalog No.: 40018-75P

Dimensions: 4.6 x 75 mm

Solvents: A: DI H_2O / 0.1% TFA (v/v)
B: Acetonitrile / 0.1% TFA (v/v)

Gradient:

time (min.)	%B
0	5
1	5
6	50
7	5

Post Time: 3 min (3.3 column volumes)

Injection vol.: 2µL

Flow rate: 1.0 mL/min

Detection: UV 214 nm (0-4.5 min), 285 nm (4.5-10 min)

Sample: The stock solution was prepared by dissolving 1.0 mg of standards in 10.00 mL of the mobile phase (50%A/50%B). The solution was then filtered with a 0.45 micron nylon syringe filter (MicroSolv Tech Corp.). The injection sample was diluted 1 : 10.

Peaks: 1. Ephedrine
2. Guaifenesin

t_0: 0.9 min

Discussion

These two compounds are used together in the Primatene formulation for the purpose of treating bronchial asthma. The separation obtained is excellent and illustrates the application of the Cogent Bidentate C18 column in analysis of a real formulation. A wavelength change was used in order to make the two peak heights more comparable (there is much more guaifenesin than ephedrine in the tablet).

Data from two column lots is shown in the figure in order to demonstrate the stationary phase reproducibility.

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