

IC Application Note No. U-11

Title: N-acetylcysteine in medication against sinusitis according to USP

Summary: Determination of N-acetylcysteine and phenylalanine in tablets against sinusitis by anion chromatography with UV/VIS detection according to USP.

Sample: Effervescent tablet containing N-acetylcysteine

Sample Preparation: Dissolution in 0.5 g/L sodium bisulfite according to USP

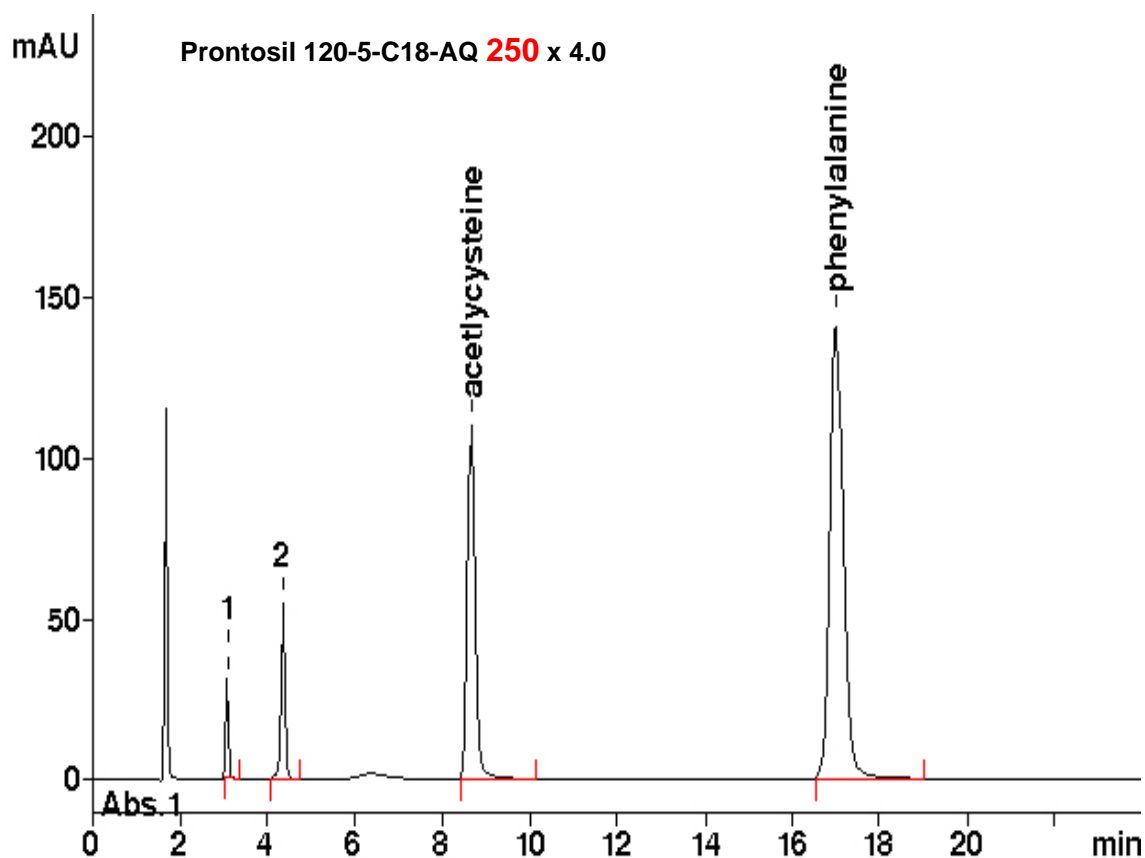
Column: Prontosil 120-5-C18-AQ 250 x 4.0 – or –
Prontosil 120-5-C18-AQ 150 x 4.0 (6.1008.100)

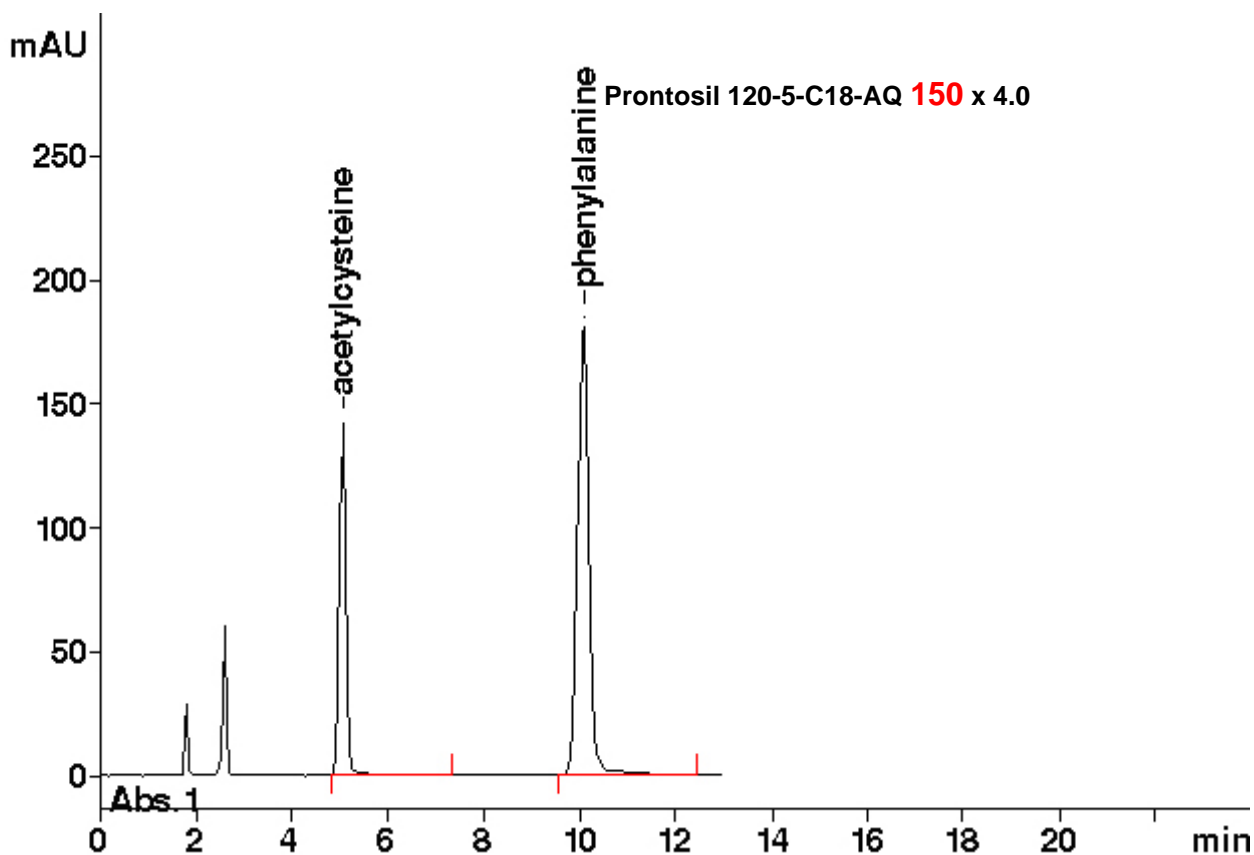
Eluent: 6.8 g/L potassium dihydrogen phosphate
pH = 3 with phosphoric acid

Wavelength: 214 nm

Flow: 1.5 mL/min

Injection Volume: 5 μ L





Results:	N-acetylcysteine	Phenylalanine
Concentration in solution	0.482 mg/mL	n.d.
Content per tablet	578 mg/tablet	

USP requirements:	Standard preparation		Assay preparation	
Relative standard deviation < 2%	0.24	fulfilled	0.2	fulfilled
Resolution > 6	20	fulfilled	20	fulfilled
Rel. retention time approx. 0.5	0.5	fulfilled	0.1	fulfilled

Remarks: In the USP a column of 3.9 x 300 mm is stipulated. In this application the column of 4.0 x 250 mm fulfilled the USP requirements by a large margin. Even the shorter 4.0 x 150 mm column fulfills all requirements. With this column the run time can be reduced dramatically.