

IC Application Note No. U-33

Title: Assay of theophylline tablets according to the USP method

Summary: Determination of theophylline and theobromine according to USP 28-NF 23 (second supplement) using RP chromatography with UV detection.

Sample: Theophylline tablets

Sample Preparation: Tablets dissolved according to USP procedure

Column: 6.1008.100 Prontosil 120-5-C18 AQ 150

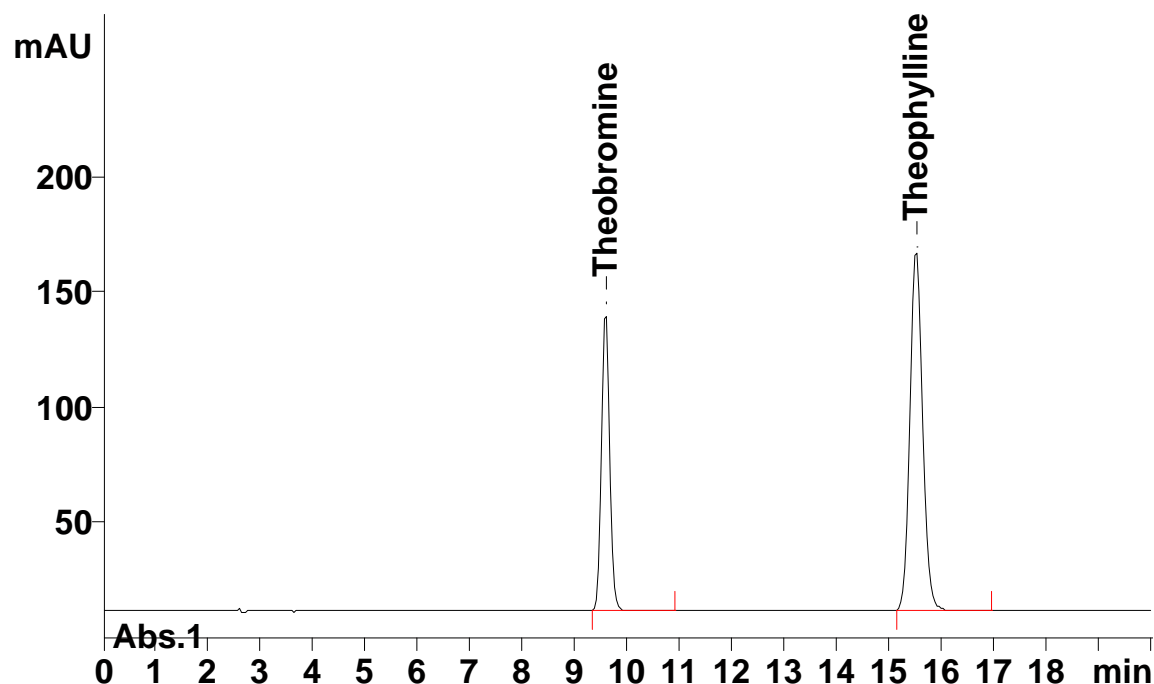
Wavelength: 280 nm

Buffer: 1.36 g/L sodium acetate, 5 mL/L glacial acetic acid

Eluent: 70 mL acetonitrile diluted with buffer to 1000 mL

Flow: 1.0 mL/min

Injection Volume: 10 μ L



Chromatogram:	Theobromine (internal standard) mg/mL	Theophylline mg/mL
	0.085	0.100

Results:

Test factors	Value	Limit	Result
Tailing factor	1.1	Less than 2.0	PASS
RSD (n = 3)	0.52%	Less than 1.5%	PASS
Resolution	16.6	More than 2	PASS

Sample assay:

Run	Concentration (mg/mL)
Sample 1-3	0.100
Sample 2-3	0.100
Sample 3-3	0.100
Average	0.100