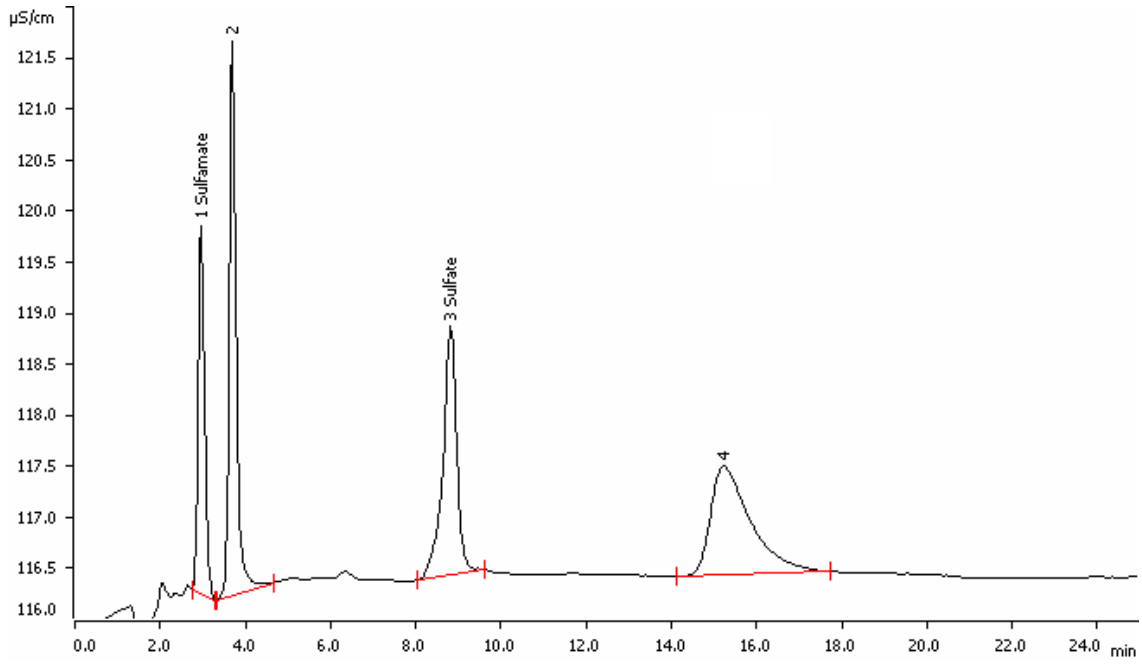
IC Application Note S–286

Sulfate and sulfamate analysis in Topiramate as per USP 33 - NF 28 Suppl. 1



Topiramate is an antiepilepsy drug. According to USP Topiramate tablets have to be tested for impurities. The determination of sulfate and sulfamate is mentioned under 'Specific Tests'. The isocratic method applies a column eluent combination primarily used for non-suppressed IC. But as sulfamate shows a negative peak under theses conditions the use of suppression is advantageous.

Results

Topiramate tablets	Result	USP limit
Sulfamate	0.06%	< 0.25%
Sulfate	0.04%	< 0.25%

Metrohm

Method description

Sample

Topiramate tablets

Sample preparation

Grind 20 tablets. Dissolve 300 mg in 50 mL of eluent according to USP.

Column

Hamilton PRP-X 100 - 250/4.0	6.1005.010
PRP-X100 guard column cartridge/4.0	6.1005.020
Dual cartridge holder	6.2821.050

Solutions

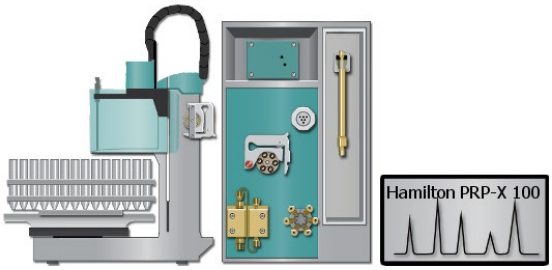
Eluent	5.8 mmol/L 4-hydroxibenzoic acid 2.5% methanol pH = 9.4 (NaOH)
Regenerant	50 mmol/L sulfuric acid
Rinsing solution	Ultrapure water

Analysis

Suppressed conductivity

Parameters

Flow rate	1.5 mL/min
Injection volume	100 µL
P_{max}	15.0 MPa
Recording time	20 min



Instrumentation

882 Compact IC plus – Anion	2.882.0020
858 Professional Sample Processor	2.858.0020

Peak table

Peak Number	Component
1	Sulfamate
2	Unknow
3	Sulfate
4	Unknown

USP Citeria

Relative standard deviation

Component	Rel.std. dev.	USP citeria
Sulfamate	2.3%	< 15%
Sulfate	2.6%	< 15%

Relative retention time (t')

Component	t'	USP citeria
Sulfamate/sulfate	0.34	Approx. 0.4