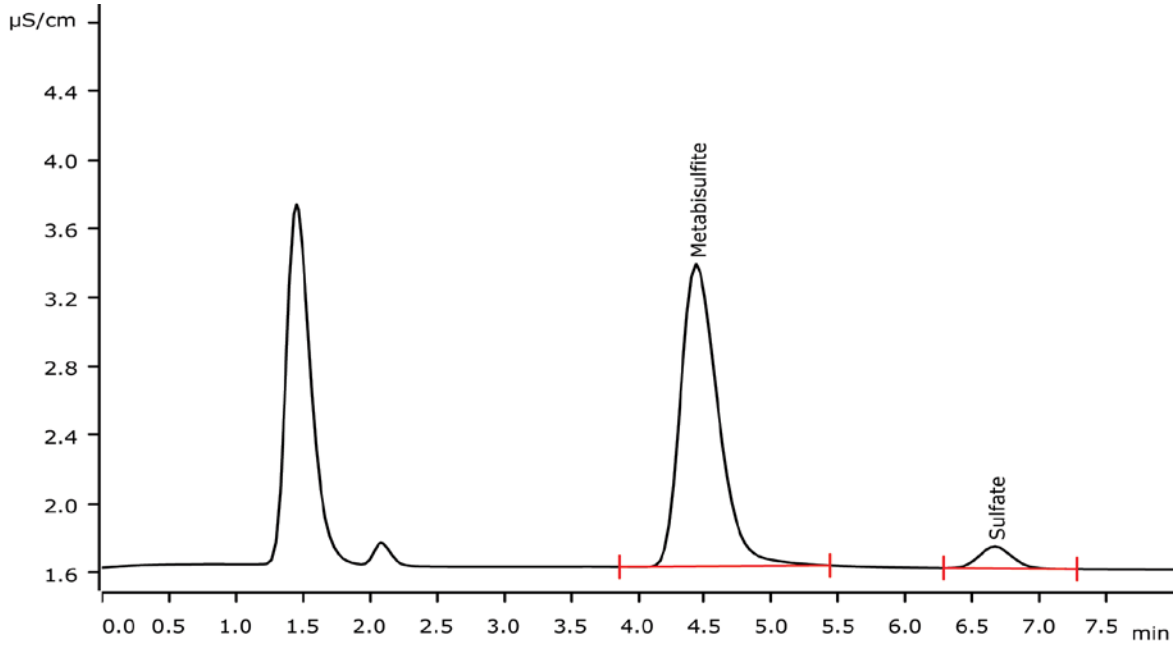
IC Application Note S–330

Metabisulfite as sulfite in pharmaceutical ointments



Sodium metabisulfite or pyrosulfite is used as preservative and antioxidant in pharmaceutical products. In water metabisulfite is not stable and is rapidly converted to sulfite. The peak in the chromatogram is the sulfite. But the method is calibrated with metabisulfite standard solutions. Therefore, the results are given as metabisulfite. This Application Note describes the determination of metabisulfite as sulfite in an ointment. The ointment is dissolved in an aqueous solution containing formaldehyde to prevent sulfite from further oxidation.

Results

Anion	Concentration*) [mg/L]	Concentration**) [g/kg]	Recovery [%]
Metabisulfite	15.0	-	103
Sodium metabisulfite	-	1.008	-
Sulfate	n.q.	-	-

*) in the injected solution **) in ointment

Metrohm

Sample

Ointment

Sample preparation

1 g of ointment are dissolved in 100 mL of solvent.

Columns

Metrosep A Supp 10 - 50/4.0	6.1020.050
Metrosep RP 2 Guard/3.5	6.1011.120

Solutions

Eluent	6.0 mmol/L sodium carbonate 4.0 mmol/L sodium hydrogen carbonate
Solvent	0.5 mL/L formaldehyde (37%) 2.0 mmol/L sodium carbonate 0.75 mmol/L sodium hydrogen carbonate
Suppressor regenerant	100 mmol/L sulfuric acid
Rinsing solution	STREAM

Analysis

Conductivity detection after sequential suppression

Instrumentation

940 Professional IC Vario ONE/SeS/PP	2.940.1500
IC Conductivity Detector	2.850.9010
858 Professional Sample Processor	2.858.0020
MSM-HC Rotor A	6.2842.000

Parameters

Flow rate	1.0 mL/min
Injection volume (MiPT)	20 µL
P_{max}	25 MPa
Recording time	8 min
Column temperature	45 °C