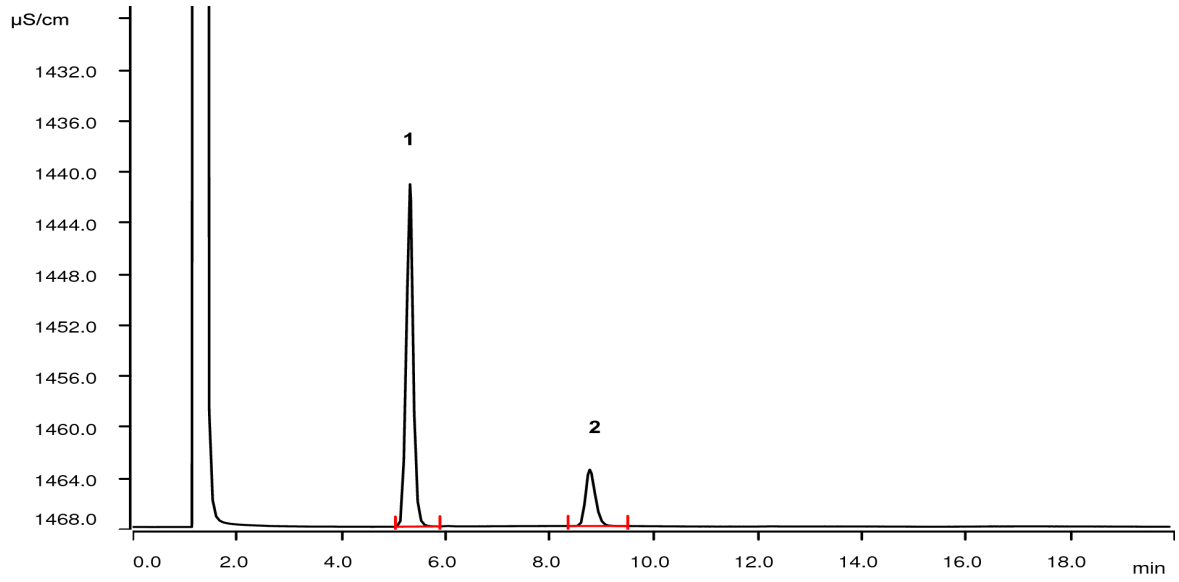
IC Application Note C–184

Potassium and sodium in bicarbonates and citric acid effervescent tablets for oral solution as per USP



Within the scope of the USP monograph modernization, potassium and sodium are determined in bicarbonates and citric acid effervescent tablets for oral solution applying cation chromatography with direct conductivity detection. The separation is performed on a Metrosep C 6 - 150/4.0 column (L76). All acceptance criteria are fulfilled. The USP41 monograph for "Potassium and sodium bicarbonates and citric acid effervescent tablets for oral solution" performs the assay of potassium by flame photometry.

Results

	Cation	Sample weighed in [mg/L]	Conc. measured [mg/L]	RSD [%, N = 6] (NMT = 1.0%)	Recov. [%] (90%...110%)	Tailing (NMT = 2.0)
1	Sodium	10.00	10.63	0.08	106.3	1.0
2	Potassium	4.68	4.74	0.27	101.2	1.2

NMT = not more than

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Sample

Potassium and sodium bicarbonates and citric acid effervescent tablets for oral solution.

Sample preparation

Stock solution: 27.6 g dissolved in 1000 mL ultrapure water.
15.0 mg/L sample solution: dilute 1 mL of stock solution to 50 mL with ultrapure water.

Columns

Metrosep C 6 - 150/4.0	6.1051.420
Metrosep C 6 Guard/4.0	6.1051.500

Solutions

Eluent	4.0 mmol/L nitric acid
Diluent	Ultrapure water (dionized water, NLT resistivity 18 MΩ•cm and less than 20 ppb Total Organic Carbon at 20 °C)
Standard	4.5 mg/L potassium from USP potassium chloride RS 10.0 mg/L Sodium from USP sodium chloride RS in Diluent

Instrumentation

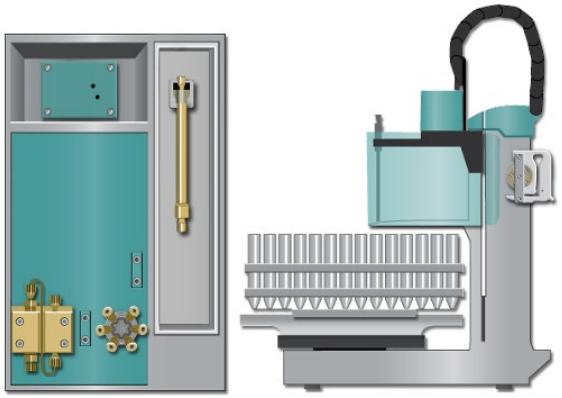
930 Compact IC Flex Oven/Deg	2.930.2160
IC Conductivity Detector	2.850.9010
858 Professional Sample Processor	2.858.0020

Analysis

Direct conductivity detection

Parameters

Flow rate	0.9 mL/min
Injection volume	20 µL
P_{max}	20 MPa
Total recording time	20 min
Column temperature	30 °C



Calibration

	Potassium [mg/L]	Sodium [mg/L]
Level 1	1.10	2.5
Level 2	2.25	5.0
Level 3	3.40	7.5
Level 4	4.50	10.0
Level 5	5.60	12.5
Level 6	6.75	15.0
Correlation coefficient	1.000 (NLT = 0.999)	1.000 (NLT = 0.999)

NLT = not less than

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