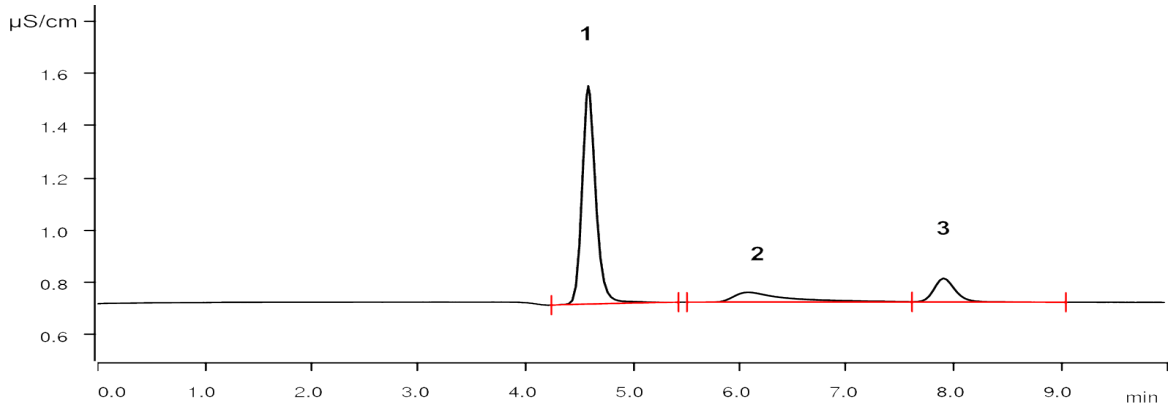
IC Application Note S–374

Fluoride Identification and Assay in «Sodium Fluoride Oral Solution» by Ion Chromatography as per USP



Fluoride is commonly used in dental products to help prevent tooth decay. If the products are intended to prevent the formation of cavities (carries), then it is regulated by the US Food and Drug Administration (USFDA) as an Over-the-Counter (OTC) Drug.
Previously, the assay of Fluoride in oral solution was done by Ion selective electrode and identification was done by tedious wet chemistry method. USP has updated this monograph for Assay and identification tests with Ion Chromatography using L46 packing. The Metrosep A Supp 1 - 250/4.6 column fulfills all USP acceptance criteria. It therefore is a viable alternative separation column for the determination of sodium fluoride in oral solutions.

Results

	Anion	Sample as NaF weighed in [mg/L]	Conc. measured [mg/L]	Resolution F^- / Cl^- (NLT = 1.5)	Tailing (NMT = 2.0)	Recov. [%] (90...110%)
1	Fluoride	1.10	1.09	11.4	1.2	98.8
2	unknown	-	-			
3	Chloride	-	n.q.			

n.q. = not quantified, NMT = not more than, NLT = not less than

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Sample

Oral solution.

Sample preparation

A portion of the oral solution corresponding to 1.1 µg/mL sodium fluoride is dissolved in ultrapure water. Injection applying Metrohm Inline Ultrafiltration.

Columns

Metrosep A Supp 1 - 250/4.6	6.1005.300
Metrosep A Supp 1 Guard/4.6	6.1005.340

Solutions

Eluent	150 mg/L sodium carbonate 1.0 mL/L sodium hydroxide (1 mol/L)
Regenerant	500 mmol/L sulfuric acid
Rinsing	STREAM
Water	Ultrapure water (dionized water, NLT resistivity 18 MΩ•cm and less than 20 ppb Total Organic Carbon at 20 °C)
System suitability solution	1.0 µg/mL USP sodium fuoride RS 0.5 µg/mL USP sodium Chloride in Diluent
Standard solution	1.1 µg/mL USP sodium fuoride RS

Instrumentation

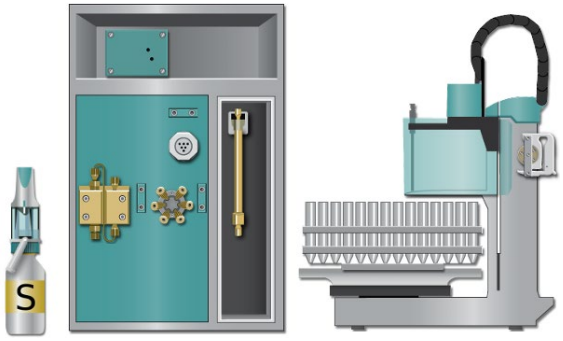
940 Professional IC Vario ONE/SeS	2.940.1100
IC Conductivity Detector	2.850.9010
800 Dosino	
858 Professional Sample Processor	2.858.0020
MSM-HC Rotor A	6.2832.000
IC equipment: Dosino regeneration	6.5330.190

Analysis

Conductivity detection after sequential suppression

Parameters

Flow rate	1.0 mL/min
Injection volume	20 µL
P_{max}	15 MPa
Run time	10 min
Column temperature	30 °C



Suitability requirements

Parameter	Required	Found
Resolution	NLT = 1.5	11.4
Tailing factor	NMT = 2.0	1.2
RSD [%]	NMT = 2.0%	1.3%

Remark

A single method for ID and assay improves productivity in QA/QC lab. Metrohm Inline Ultrafiltration improves column life.

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