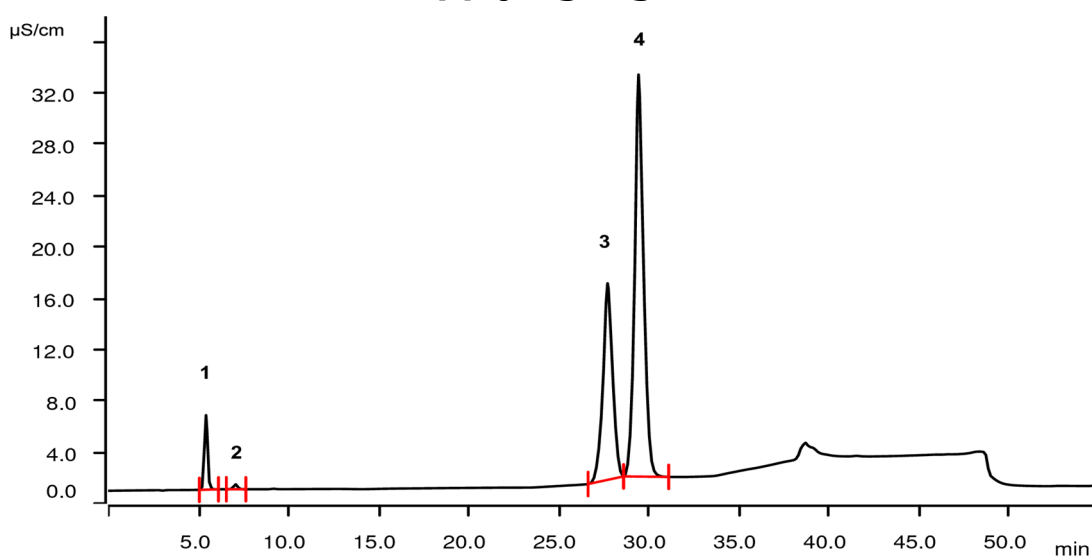


## IC Application Note S-380

# Assay of sodium monofluorophosphate for pharmaceutical use

USP monograph modernization initiative: ion chromatography applying a hydroxide eluent on a Metrosep A Supp 16 - 250/4.0 column (L91) applying a gradient



Chromatogram of the System Suitability Test for assay.

Sodium monofluorophosphate for pharmaceutical use needs to comply with USP requirements. The actual monograph (USP 42) uses three different methods for the identification, the impurity, and the assay. Ion chromatography allows the analysis of these three parameters in one single determination. In the course of the USP monograph modernization, this ion chromatographic approach makes this type of analysis even easier.

## Results

Anion	Sample ID	Result [%]	USP limit [%]	Conc. SST [mg/L]
1 Fluoride	Impurity	n.q.		4.0
2 Acetate	Impurity	n.q.		1.4
3 Monofluorophosphate	Assay [%]	95.6	91.7-100.5	150
4 Sulfate	impurity	n.q.		150

n.q. = not quantified. SST = system suitability test, concentrations as sodium salts. For further results, see next page.

## Sample

Sodium monofluorophosphate

## Sample preparation

Dissolve in ultrapure water to a nominal concentration of 150 mg/L.

## Columns

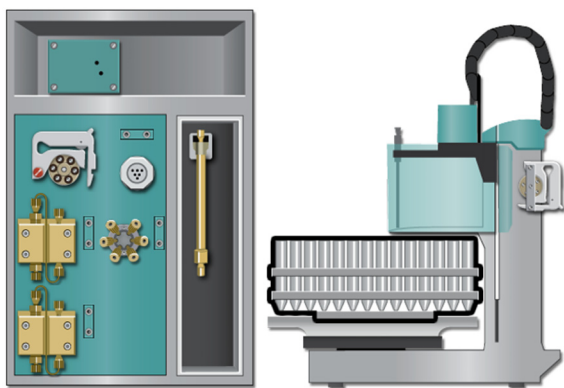
Metrosep A Supp 16 - 250/4.0	6.1031.430
Metrosep A Supp 16 Guard/4.0	6.1031.500

## IC Solutions

Eluent A	100 mmol/L potassium hydroxide
Eluent B	Ultrapure water
Regenerant	100 mmol/L sulfuric acid
Rinsing	Ultrapure water

## Instrumentation

940 Professional IC Vario One/SeS/PP/HPG	2.940.1540
IC Conductivity Detector	2.850.9010
858 Professional Sample Processor	2.858.0020
MSM Rotor A	6.2832.000
Adapter sleeve for Suppressor Vario	6.2842.020



## Analysis

Conductivity detection after sequential suppression

## Parameters IC

Flow rate	1.0 mL/min
Injection volume (MiPT)	10 µL
P <sub>max</sub>	20 MPa
Column temperature	40 °C
Recording time	55 min

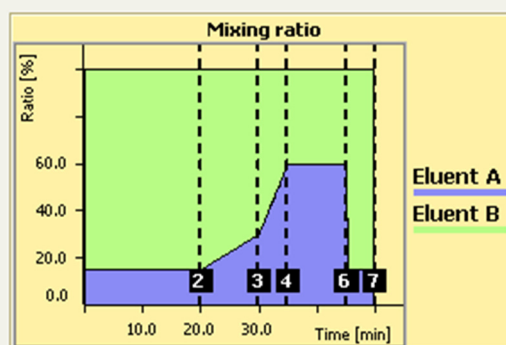
## System suitability requirements for assay

USP Parameter	Result	USP required	Remarks
Resolution PFO <sub>3</sub> <sup>2-</sup> /SO <sub>4</sub> <sup>2-</sup>	NLT 1.5	1.84	Pass
Tailing factor PFO <sub>3</sub> <sup>2-</sup>	NMT 2.5	1.02	Pass
RSD PFO <sub>3</sub> <sup>2-</sup> [%; n=6)	NMT 2.0%	0.38	Pass

## Gradient

### Gradient

	Time [min]	Eluent A [%]	Eluent B [%]	Curve	Flow
▶ 1	Start	15	85		1.0
2	20.0	15	85	Linear	1.0
3	30.0	30	70	Linear	1.0
4	35.0	60	40	Linear	1.0
5	45.0	60	40	Linear	1.0
6	45.1	15	85	Linear	1.0
7	50.0	15	85	Linear	1.0
8					



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