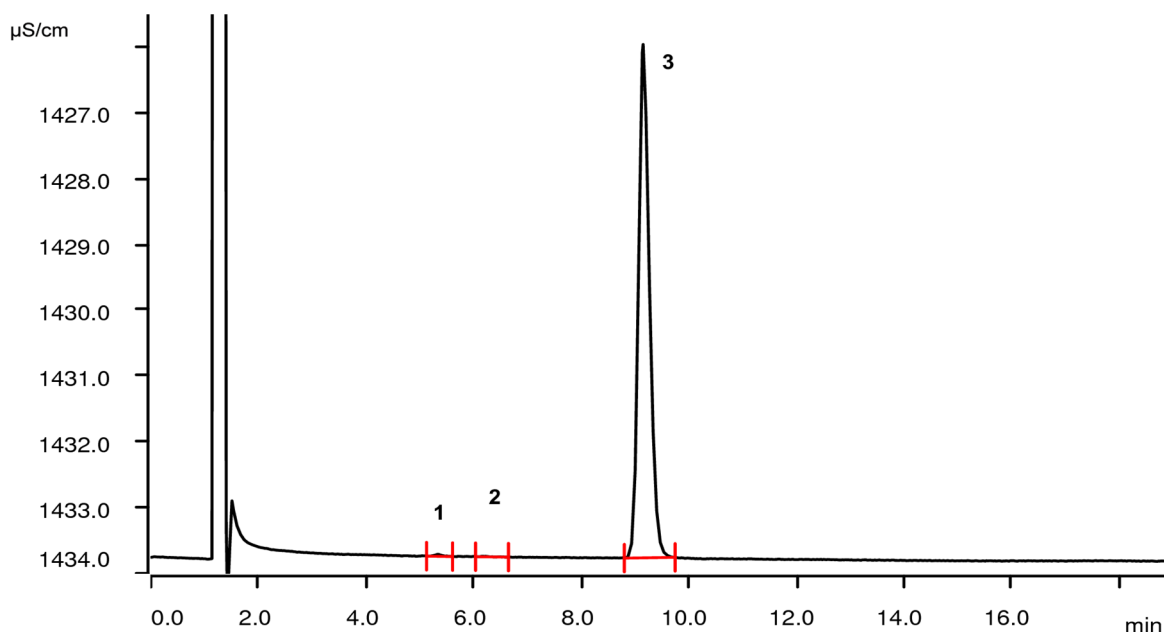


# Ammonium impurities in potassium bitartrate

**USP monograph modernization: ion chromatography applying a nitric acid eluent on a Metrosep C 6 - 150/4.0 column (L76).**



Cation chromatogram of potassium bitartrate.

Potassium bitartrate for pharmaceutical use must comply with USP requirements. The actual monograph (USP 42) uses a colorimetric method for the determination of ammonium impurities. Ion chromatography allows the measurement in a single determination under the same conditions used for the potassium assay (see AN-C-181). In the course of the USP monograph modernization, this ion chromatographic approach makes this type of analysis even easier.

## Results

Cation	Conc. measured	Signal to noise (NLT = 20)	RSD [%, N = 6]	Resolution (NLT = 2.0)	Tailing factor (NMT = 2.0)
2 Ammonium	23.8 µg/L	60	5.1	-	1.06
3 Potassium	15.0 mg/L	-	-	-	-

Peak 1 corresponds to a trace amount of sodium present in the sample. NLT = not less than, NMT = not more than.

## Sample

Potassium bitartrate

## Sample preparation

Stock solution: 180.3 mg dissolved in 50 mL ultrapure water.

15.0 mg/L sample solution: dilute 1 mL of stock solution to 50 mL with ultrapure water.

## Cation 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 M $\Omega$ ·cm and less than 20 ppb Total Organic Carbon at 20 °C)
Standard	15.0 mg/L potassium from USP potassium 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 $\mu$ L
P <sub>max</sub> (cations)	20 MPa
Column temperature	30 °C
Recording time	19 min

