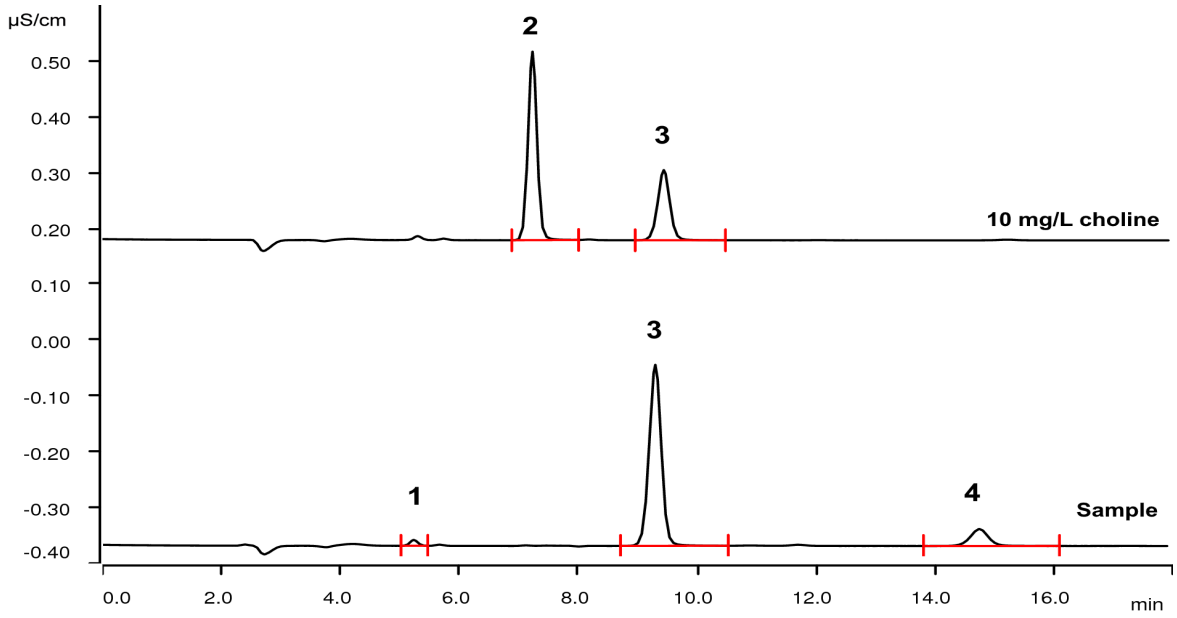
IC Application Note CS–015

Limit of choline in succinylcholine on a Metrosep C Supp 1 - 150/4.0 closely following USP



Succinylcholine is a short-term paralyzing agent used e.g., for tracheal intubation. Choline is a building block of the drug and needs to be determined as an impurity. USP applies cation chromatography with conductivity detection after suppression. Eluent composition and column type do not exactly comply with the USP method. However, the results fulfill the respective requirements. The choline concentration of the sample is out of USP specifications.

Results

	Cation	Conc.* [mg/L]	Reporting Conc. [%]	RSD* [%, N = 3]	RSD** [%, N = 8] NMT[1] = 3.0	Resolution** (K - choline) NLT[2] = 5.0
1	Sodium	n.q	-	-	-	-
2	Potassium	n.q	-	-	-	-
3	Choline	465	0.93	0.5	0.5	6.79
4	Calcium	n.q	-	-	-	-

* in sample solution, ** system suitability, n.q. = not quantified
[1] NMT = not more than [2] NLT = not less than

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Sample

Succinylcholine solution (50 mg/mL), not for pharmaceutical use

Sample preparation

Dilution 1 : 20 with ultrapure water.

Columns

Metrosep C Supp 1 - 150/4.0	6.1052.420
Metrosep C Supp 1 Guard/4.0	6.1052.500

Solutions

Eluent	4.0 mmol/L nitric acid 50 µg/L rubidium 4.8% acetonitrile
Eluent concentrate	100 mmol/L nitric acid 1 mg/L rubidium
Eluent diluent	5% acetonitrile
Suppressor regenerant	70 mmol/L sodium carbonate 70 mmol/L sodium hydrogen carbonate 30% acetonitrile
Rinsing solution	STREAM
Column wash solution	15 mmol/L nitric acid 30% acetonitrile

Parameters

Flow rate	1.0 mL/min
Injection volume	5 µL (pick-up mode)
P_{max}	15 MPa
Recording time	18 min
Column temperature	40 °C
Sample temperature	4 °C
Dosino suppression	0.5 mL/min for 10 min

Analysis

Conductivity detection after sequential suppression

Instrumentation

930 Compact IC Flex Oven/SeS/Deg	2.930.2460
IC Conductivity Detector	2.850.9010
889 IC Sample Center - cool	2.889.0020
800 Dosino (Dosino regeneration)	2.800.0010
MSM-HC Rotor C	6.2842.200
IC equipment: Dosino regeneration	6.5330.190

Remark

Over time, contaminations are retained on the analytical column. To increase the lifetime of the column, it is recommended to flush the column with 30 mL of the column wash solution when the back ground conductivity get higher than 0.2 µS/cm. The MSM needs to be disconnected for this procedure.

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