



S E R A T E C

COPIE CERTIFIEE CONFORME

A L'ORIGINAL

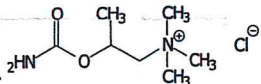
LE : 15/02/19

PAR L'ASSURANCE QUALITE SGO

BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

V01

SPE n° CQ - 088, vs 14



$C_7H_{17}ClN_2O_2$

CAS RN [590-63-6] - EINECS : 209-686-8

M.W. = 196.67 g.mol⁻¹

1-Propanaminium, 2-[(aminocarbonyloxy)-N,N,N-trimethyl-, chloride
(±)-(2-Hydroxypropyl)trimethylammonium chloride carbamate

BATCH N° BTHA-136

TESTS	METHODS	SPECIFICATIONS	RESULTS
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CHARACTERS	Visually MOD n°: CQ - 673	White crystalline powder	White crystalline powder
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IDENTIFICATION			
A: Infrared absorption	USP (197M) MOD n°: CQ - 673	Conform to spectrum of <i>Bethanechol chloride reference standard</i>	Complies
B: Chromatographic retention time	USP <621> MOD n°: CQ - 673	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Complies
C: Chloride	USP (191) MOD n°: CQ - 673	A solution of it responds to the tests	Complies

TESTS			
pH	USP (791) MOD n°: CQ - 673	5.5 - 6.5	5.9
Loss on drying	USP (731) MOD n°: CQ - 673	NMT 1.0%	0.1%
Residue on Ignition	USP (281) MOD n°: CQ - 673	NMT 0.1%	0.0%
Heavy metals	USP (231) MOD n°: CQ - 673	NMT 0.003%	Complies
Chloride content	USP MOD n°: CQ - 673	17.70% - 18.30%	18.23%
ASSAY	USP <621> MOD n°: CQ - 673	98.0% - 101.5% of $C_7H_{17}ClN_2O_2$ calculated on the dried basis	99.4%

Written by : CASALINO GEBZYNSKI		Reviewed by : S. GEORGIN	
Date : 14/02/19	Visa : SGI	Date : 15/02/19	Visa : SGO

Seratec S.A.S.

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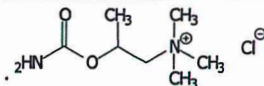
LE : 15.10.2019

PAR L'ASSURANCE QUALITÉ

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TESTS	METHODS	SPECIFICATIONS	RESULTS
Impurities/Related substances	USP <621> Seratec SOP MOD n°: CQ – 673	Desacetyl methacholine : NMT 0.2% Any individual unspecified impurity : NMT 0.1%	0.0% Not Detected
		Ammonium chloride: NMT 0.2%	< LOQ
		Total impurities: NMT 0.6%	0.1%
Residual Solvents	USP <621> Seratec SOP MOD n°: CQ – 673	Triethylamine ≤ 38 ppm	Not Detected
		Chloroform ≤ 60 ppm Methanol ≤ 300 ppm Ethanol ≤ 500 ppm Acetone ≤ 50 ppm Isopropanol ≤ 1000 ppm Acetonitrile ≤ 250 ppm	Not Detected Not Detected < LOQ Not Detected 572 ppm Not Detected
Particle Size Distribution	Seratec SOP MOD n°: CQ – 673	D (10%) NMT 10 microns D (50%) NMT 75 microns D (90%) NMT 250 microns	4 µm 18 µm 81 µm

LOQ : Limit of Quantification

MANUFACTURING DATE	February 2019
RETEST DATE	July 2020

ANALYSES	Date : February 13 th , 2019 By : A.CAUDAN/V.BACHMANN/C.COUPÉAU/ Lab Service
CONCLUSION	Compliant with current USP specifications

Written by : CASALINO GEBELZYNSKI	Reviewed by : S. GEORGIN
Date : 14/02/19 Visa : GBI	Date : 15/02/19 Visa : SGO

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