Lote - 0090118

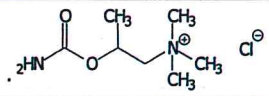
SERATEC

COPIE CERTIFIÉE CONFORME
A L'ORIGINAL
LE ...03./..01./....18...
PAR L'ASSURANCE QUALITÉ SGO

BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

V02

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-[(aminocarbonyl)oxy]-N,N,N-trimethyl-, chloride (±)-(2-Hydroxypropyl)trimethylammonium chloride carbamate		

BATCH N° BTHA-122

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%	Not Detected Not Detected
		Ammonium chloride: NMT 0.2%	Not Detected
		Total impurities: NMT 0.6%	Not Detected
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 235 ppm Not Detected Not Detected 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 19 µm 56 µm

MANUFACTURING DATE	December 2017
RETEST DATE	May 2019

ANALYSES	Date : December 27th , 2017	By : A. CAUDAN / V.BACHMANN / C. COUPEAU
CONCLUSION	**Compliant with current USP specifications**	

Written by : BEAUD		Reviewed by : S. GEORGIN	
Date : 28/12/17	Visa : JBE	Date : 03/01/18	Visa : SGO

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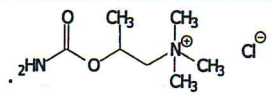

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BATCH N° BTHA-122

TESTS	METHODS	SPECIFICATIONS	RESULTS
CHARACTERS	Visually MOD n°: CQ - 673	White crystalline powder	White crystalline powder
IDENTIFICATION			
A: Infrared absorption	USP ⟨197M⟩ MOD n°: CQ – 673	Conform to spectrum of *Bethanechol chloride reference standard*	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	5.7
Loss on drying	USP ⟨731⟩ MOD n°: CQ – 673	NMT 1.0%	0.0%
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%	17.90%
ASSAY	USP <621> MOD n°: CQ – 673	98.0% - 101.5% of $C_7H_{17}ClN_2O_2$ calculated on the dried basis	100.6%

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