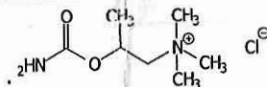


J. SEBILLOT *JS*
BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

V01

SPE n° CQ - 088, vs 15


 $C_7H_{17}ClN_2O_2$

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

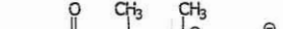
BATCH N° BTHA-150

TESTS	METHODS	SPECIFICATIONS	RESULTS
CHARACTERS	MOD n°: CQ - 673	White crystalline powder	White crystalline powder
IDENTIFICATION			
A: Infrared absorption	MOD n°: CQ - 673	Conform to spectrum of <i>Bethanechol chloride USP reference standard</i>	Complies
B: Chromatographic retention time	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	MOD n°: CQ - 673	A solution of it responds to the tests	Complies
TESTS			
pH	MOD n°: CQ - 673	5.5 - 6.5	6.4
Loss on drying	MOD n°: CQ - 673	NMT 1.0%	0.3%
Residue on Ignition	MOD n°: CQ - 673	NMT 0.1%	0.0%
Chloride content	MOD n°: CQ - 673	17.70% - 18.30%	18.12%
ASSAY	MOD n°: CQ - 673	98.0% - 101.5% of $C_7H_{17}ClN_2O_2$ calculated on the dried basis	100.4%

Written by : Julie Sébillot		Reviewed by : Maria Moreno	
Date : 14/12/20	Visa : <i>JSE</i>	Date : 15/12/20	Visa : <i>TH</i>

BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

V01

			SPE n° CQ - 088, vs 15
C ₇ H ₁₇ ClN ₂ O 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 carbanate			

BATCH N° BTHA-150

TESTS	METHODS	SPECIFICATIONS	RESULTS
Impurities/Related substances	MOD n°: CQ - 673	Desacetyl methacholine : NMT 0.2% Any individual unspecified impurity : NMT 0.1%	< LOD Not Detected
		Ammonium chloride: NMT 0.2%	< LOD
		Total impurities: NMT 0.6%	0.0%
Residual Solvents	MOD n°: CQ - 673	Triethylamine ≤ 38 ppm	Not Detected
		Chloroform ≤ 60 ppm	Not Detected
		Methanol ≤ 300 ppm	Not Detected
		Ethanol ≤ 500 ppm	281 ppm
		Acetone ≤ 50 ppm	Not Detected
		Isopropanol ≤ 1000 ppm	77 ppm
Particle Size Distribution	MOD n°: CQ - 673 LAB SERVICE	D (10%) NMT 10 microns	10 µm
		D (50%) NMT 75 microns	28 µm
		D (90%) NMT 250 microns	109 µm

NMT: Not More Than

MANUFACTURING DATE	October 2020		
RETEST DATE	April 2022		
ANALYSES	Date : 02/12/2020 By : A. MANCEAU/ A. CAUDAN/ A. NEVEU/ LABSERVICE		
CONCLUSION	Compliant with current specification		
Written by : Julie Sébillot		Reviewed by : Maria Moreno	
Date : 14/12/20	Visa : JSE	Date : 15/12/20	Visa : JM