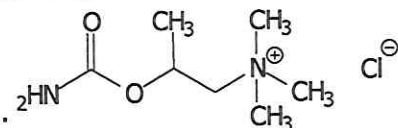


29/09/2021

BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

V02

SPE n° CQ - 165, vs 06



C₇H₁₇ClN₂O₂

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-151

TESTS	METHODS	SPECIFICATIONS	RESULTS
CHARACTERS	Visual examination MOD n°: CQ - 673	White crystalline powder	White crystalline powder
IDENTIFICATION			
A: Infrared absorption	USP (197M) MOD n°: CQ - 673	Conform to spectrum of <i>Bethanechol chloride USP 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	5.8
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) Method I MOD n°: CQ - 673	NMT 0.003%	<0.003%
Chloride content	USP MOD n°: CQ - 673	17.70% - 18.30%	18.17%
ASSAY	USP MOD n°: CQ - 673	98.0% - 101.5% of C ₇ H ₁₇ ClN ₂ O ₂ calculated on the dried basis	100.8%

NMT: Not More Than

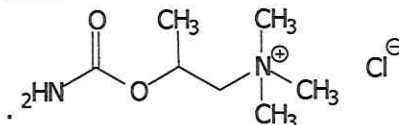
Written by : Antoine Jugnet		Reviewed by : Sophie Gerogin	
Date : 26/11/20	Visa : <i>AJ</i>	Date : 26/11/20	Visa : <i>SGO</i>

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BATCH N° BTHA-151

TESTS	METHODS	SPECIFICATIONS	RESULTS
ADDITIONAL TESTS			
Impurities/Related substances	MOD n°: CQ – 673	Desacetyl methacholine : NMT 0.3 %	Not detected
		Any individual unspecified impurity : NMT 0.1 %	Not detected
		Ammonium chloride : NMT 0.5 %	Not detected
		Total impurities : NMT 1.0 %	0.0%
Residual Solvents	MOD n°: CQ – 673	Triethylamine ≤ 400 ppm	Not detected
	USP (621) MOD n°: CQ – 673	Chloroform ≤ 60 ppm Methanol ≤ 3000 ppm Ethanol ≤ 5000 ppm Acetone ≤ 5000 ppm Isopropanol ≤ 5000 ppm Acetonitrile ≤ 410 ppm	Not detected Not detected (13 ppm) 123 ppm Not detected Not detected Not detected

NMT: Not More Than

MANUFACTURING DATE	September 2020
RETEST DATE	September 2022

ANALYSES	Date : 22/10/20 By : A. NEVEU/ A. MANCEAU/ C. COUPEAU/ A. CAUDAN/ LABSERVICE
CONCLUSION	Compliant with current USP specification

Written by : Antoine Jugnet		Reviewed by : Sophie Georgin	
Date : 26/11/20	Visa : AS	Date : 26/11/20	Visa : SGO