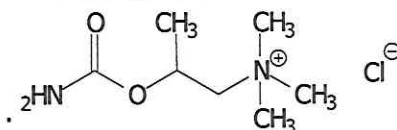


CERTIFICATE OF ANALYSIS - BETHANECHOL CHLORIDE USP

V01

1/2

SPE n° CQ - 088, vs 16



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-168

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 Bethanechol chloride reference standard	Comply
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	Comply
C: Chloride	MOD n°: CQ – 673	A solution of it responds to the tests	Comply
TESTS			
pH	MOD n°: CQ – 673	5.5 – 6.5	5.7
Loss on drying	MOD n°: CQ – 673	NMT 1.0%	0.2%
Residue on ignition	MOD n°: CQ – 673	NMT 0.1%	0.0%
Chloride content	MOD n°: CQ – 673	17.70% - 18.30%	18.26%
ASSAY	MOD n°: CQ – 673	98.0% - 101.5% of C ₇ H ₁₇ ClN ₂ O ₂ calculated on the dried basis	100.9%

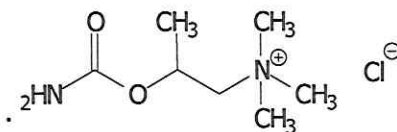
Written by : Coraline COUPEAU		Reviewed by : J. SEBILLOT	
Date : 30/05/2023	Visa : <i>ce</i>	Date : 02/06/23	Visa : <i>JSE</i>

CERTIFICATE OF ANALYSIS - BETHANECHOL CHLORIDE USP

V01

2/2

SPE n° CQ - 088, vs 16



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-168

TESTS	METHODS	SPECIFICATIONS	RESULTS
Impurities/Related substances	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%	< Limit of quantification
		Total impurities: NMT 0.6%	0.0%
Residual Solvents	MOD n°: CQ – 673	Triethylamine ≤ 400 ppm	41 ppm
		Methanol ≤ 300 ppm	< Limit of detection
		Ethanol ≤ 500 ppm	< Limit of quantification
		Acetone ≤ 50 ppm	Not detected
		Isopropanol ≤ 1000 ppm	< Limit of detection
Particle Size Distribution	MOD n°: CQ – 673 LAB SERVICE	Acetonitrile ≤ 250 ppm	Not detected
		Chloroforme ≤ 60 ppm	Not detected
		D (10%) ≤ 10 µm D (50%) ≤ 75 µm D (90%) ≤ 250 µm	4µm 20µm 75µm

MANUFACTURING DATE	May 2023
RETEST DATE	May 2025
ANALYSES	Date : 26/05/2023 By : A.NEVEU, A.CAUDAN, T.COLONNIER, A.MANCEAU, LAB SERVICE
CONCLUSION	Compliant with current specification
Written by : Coraline COUPEAU	Reviewed by : J. SEBILLOT
Date : 30/05/2023	Visa : <i>ce</i>
Date : 02/06/23	Visa : <i>JSE</i>