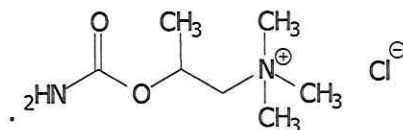


CERTIFICATE OF ANALYSIS - BETHANECHOL CHLORIDE USP
V01

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-158

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%	17.95%
ASSAY	MOD n°: CQ – 673	98.0% - 101.5% of C ₇ H ₁₇ ClN ₂ O ₂ calculated on the dried basis	101.1%

Written by : Isabelle Dorin		Reviewed by : S. GEORGIN	
Date : 20/04/2022	Visa : 	Date : 06/05/22	Visa : SGO

COPIE CERTIFIÉE CONFORME

A L'ORIGINAL

LE 20/06/22

PAR L'ASSURANCE QUALITÉ

NF

N DE LOTE:

0140722

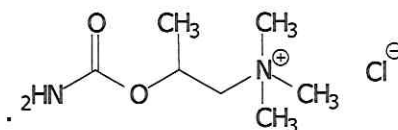
22/07/2022

BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

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-158

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%	Not detected
		Total impurities: NMT 0.6%	0.0%
Residual Solvents	MOD n°: CQ – 673	Triethylamine ≤ 400 ppm	Not detected
		Methanol ≤ 300 ppm Ethanol ≤ 500 ppm Acetone ≤ 50 ppm Isopropanol ≤ 1000 ppm Acetonitrile ≤ 250 ppm	<LOD <LOD Not detected <LOQ Not detected
		Chloroforme ≤ 60 ppm	Not detected
Particle Size Distribution	MOD n°: CQ – 673 LAB SERVICE	D (10%) ≤ 10 µm D (50%) ≤ 75 µm D (90%) ≤ 250 µm	4 µm 18 µm 53 µm

LOD=Limit of detection LOQ= Limit of quantification

MANUFACTURING DATE	March 2022		
RETEST DATE	March 2024		
ANALYSES	Date : 19/04/2022 By : L.CASSUBIE/A.NEVEU/A.CAUDAN/A.MANCEAU/I.DORIN/LabService		
CONCLUSION	Compliant with current specification		
Written by : Isabelle Dorin		Reviewed by : S. GEORGIN	
Date : 20/04/2022	Visa : 	Date : 06/05/22	Visa : 

