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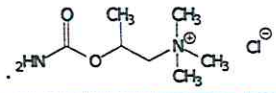
COPIE CERTIFIÉE CONFORME
A L'ORIGINAL
LE 15/09/2022
PAR L'ASSURANCE QUALITÉ
BIGOT ABE

CERTIFICATE OF ANALYSIS - BETHANECHOL CHLORIDE USP

V01

SPE n° CQ - 088, vs 16



$C_7H_{17}ClN_2O_2$	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-159

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	5.6
Loss on drying	MOD n°: CQ – 673	NMT 1.0%	0.1%
Residue on ignition	MOD n°: CQ – 673	NMT 0.1%	0.0%
Chloride content	MOD n°: CQ – 673	17.70% - 18.30%	17.92%
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 : Isabelle Dorin		Reviewed by : J. SEBILLOT	
Date : 14/09/2022	Visa :	Date : 15/09/22	Visa : JSG

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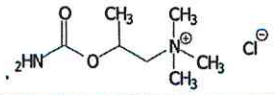

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TESTS	METHODS	SPECIFICATIONS	RESULTS
Impurities/Related substances	MOD n°: CQ – 673	Desacetyl methacholine : NMT 0.2%	Not detected
		Any individual unspecified impurity : NMT 0.1%	0.1%
		Ammonium chloride: NMT 0.2%	Not detected
		Total impurities: NMT 0.6%	0.1%
Residual Solvents	MOD n°: CQ – 673	Triethylamine ≤ 400 ppm	Not detected
		Methanol ≤ 300 ppm	Not detected
		Ethanol ≤ 500 ppm	Not detected
		Acetone ≤ 50 ppm	Not detected
		Isopropanol ≤ 1000 ppm	<LOQ
		Acetonitrile ≤ 250 ppm	Not detected
		Chloroforme ≤ 60 ppm	Not detected
Particle Size Distribution	MOD n°: CQ – 673 LAB SERVICE	D (10%) ≤ 10 µm	5 µm
		D (50%) ≤ 75 µm	20 µm
		D (90%) ≤ 250 µm	48 µm

LOQ= limit of quantification

MANUFACTURING DATE	September 2022
RETEST DATE	August 2024
ANALYSES	Date : 13/09/2022 By : C.COUPEAU / A.CAUDAN / Lab service
CONCLUSION	**Compliant with current specification**

Written by : Isabelle Dorin		Reviewed by : J. SEBILLOT	
Date : 14/09/2022	Visa :	Date : 15/09/22	Visa : JSG