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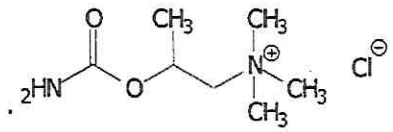
COPIE CERTIFIÉE CONFORME
A L'ORIGINAL
LE 22/12/2023
PAR L'ASSURANCE QUALITÉ
BIGOT ABI

23/01/2024

CERTIFICATE OF ANALYSIS - BETHANECHOL CHLORIDE USP

V01

SPE n° CQ - 088, vs 17



$C_7H_{17}ClN_2O_2$	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-175

TESTS	METHODS	SPECIFICATIONS	RESULTS
CHARACTERS	Visual examination	White crystalline powder	White crystalline powder
IDENTIFICATION			
A: Infrared spectrum	USP ⟨197A⟩ MOD n°: CQ – 673	Conform to spectrum of Bethanechol chloride reference standard	Compliant
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	Compliant
C: Chloride	USP <191> MOD n°: CQ – 673	A solution of it responds to the tests	Compliant
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%	0.0%
Residue on ignition	USP ⟨281⟩ MOD n°: CQ – 673	NMT 0.1%	0.0%
Chloride content	MOD n°: CQ – 673	17.70% - 18.30%	17.80%
ASSAY	MOD n°: CQ – 673	98.0% - 101.5% of $C_7H_{17}ClN_2O_2$ calculated on the dried basis	100.3%

Written by: Isabelle DORIN		Reviewed by: S. GEORGIN	
Date: 21/12/2023	Visa: ID	Date: 21/12/23	Visa: SGO

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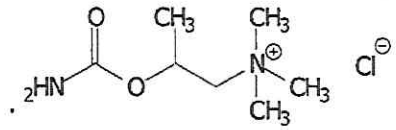

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TESTS	METHODS	SPECIFICATIONS	RESULTS
Related substances	USP ⟨621⟩ MOD n°: CQ – 673	Desacetyl methacholine: NMT 0.2% Any individual unspecified impurity: NMT 0.1%	Not detected Not detected
		Ammonium chloride: NMT 0.2%	<Limit of quantification
		Total impurities: NMT 0.6%	0.0%
Residual Solvents	USP ⟨621⟩ MOD n°: CQ – 673	Triethylamine ≤ 400 ppm	<Limit of quantification
	USP ⟨621⟩ MOD n°: CQ – 673	Methanol ≤ 300 ppm Ethanol ≤ 500 ppm Acétone ≤ 50 ppm Isopropanol ≤ 1000 ppm Acetonitrile ≤ 250 ppm	Not detected Not detected Not detected <Limit of quantification 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 52 µm

MANUFACTURING DATE	December 2023
RETEST DATE	November 2025

ANALYSES	Date: 20/12/2023 Labservice	By: A.MANCEAU / A.NEVEU / A.CAUDAN / C.COUPEAU /
CONCLUSION	**Compliant with current specification**	

Written by: Isabelle DORIN		Reviewed by: S. GEORGIN	
Date: 21/12/2023	Visa:	Date: 21/12/23	Visa: SGD