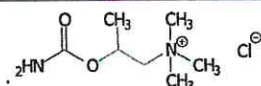


CERTIFICATE OF ANALYSIS - BETHANECHOL CHLORIDE USP

V01

1/2

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-[(aminocarbonyloxy)-N,N,N-trimethyl-, chloride (±)-(2-Hydroxypropyl)trimethylammonium chloride carbamate		

BATCH N° BTHA-162

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%	0.1%
Chloride content	MOD n°: CQ – 673	17.70% - 18.30%	18.09%
ASSAY	MOD n°: CQ – 673	98.0% - 101.5% of $C_7H_{17}ClN_2O_2$ calculated on the dried basis	99.6%

Written by : Isabelle Dorin	Reviewed by : J. SEBILLOT
Date : 14/11/2022	Visa : JSC