

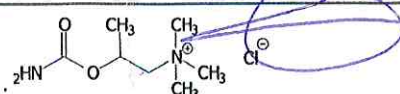
**METAPHARMACEUTICAL**

N DE LOTE: 0111221

**BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS**

VOI

1/2

			SPE n° CQ - 088, vs 15
C <sub>7</sub> H <sub>17</sub> ClN <sub>2</sub> O <sub>2</sub>	CAS RN [590-63-6] – EINECS : 209-686-8	M.W. = 196.67 g.mol <sup>-1</sup>	
1-Propanaminium, 2-[(aminocarbonyl)oxy]-N,N,N-trimethyl-, chloride (±)-(2-Hydroxypropyl)trimethylammonium chloride carbamate			

**BATCH N° BTHA-154**

TESTS	METHODS	SPECIFICATIONS	RESULTS
<b>CHARACTERS</b>	MOD n°: CQ - 673	White crystalline powder	White crystalline powder

**IDENTIFICATION**

<b>A: Infrared absorption</b>	MOD n°: CQ - 673	Conform to spectrum of <i>Bethanechol chloride USP reference standard</i>	Comply
<b>B: Chromatographic retention time</b>	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
<b>C: Chloride</b>	MOD n°: CQ - 673	A solution of it responds to the tests	Comply

**TESTS**

<b>pH</b>	MOD n°: CQ - 673	5.5 – 6.5	6.0
<b>Loss on drying</b>	MOD n°: CQ - 673	NMT 1.0%	0.0%
<b>Residue on Ignition</b>	MOD n°: CQ - 673	NMT 0.1%	0.0%
<b>Chloride content</b>	MOD n°: CQ - 673	17.70% - 18.30%	17.88%

<b>ASSAY</b>	MOD n°: CQ - 673	98.0% - 101.5% of C <sub>7</sub> H <sub>17</sub> ClN <sub>2</sub> O <sub>2</sub> calculated on the dried basis	101.0%
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Written by : Isabelle Dorin

Reviewed by : Sophie GEORGIN

Date : 18/10/2021

Visa : 

Date : 05/11/21

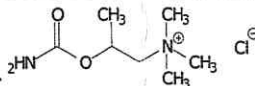
Visa : 

**BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS**

V01

2/2

SPE n° CQ - 088, vs 15


 $C_{17}H_{17}ClN_2O_2$ 


CAS RN [590-63-6] – EINECS : 209-686-8

 M.W. = 196.67 g.mol<sup>-1</sup>

 1-Propanaminium, 2-[(aminocarbonyloxy)-N,N-trimethyl-, chloride  
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**BATCH N° BTHA-154**

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 0.0%
		Ammonium chloride: NMT 0.2%	Not detected
		Total impurities: NMT 0.6%	0.0%
Residual Solvents	MOD n°: CQ – 673	Triethylamine ≤ 38 ppm	Not detected
		Chloroform ≤ 60 ppm	Not detected
		Methanol ≤ 300 ppm	Not detected
		Ethanol ≤ 500 ppm	<LOQ
		Acetone ≤ 50 ppm	Not detected
		Isopropanol ≤ 1000 ppm Acetonitrile ≤ 250 ppm	Not detected Not detected
Particle Size Distribution	MOD n°: CQ – 673 LAB SERVICE	D (10%) NMT 10 microns	4µm
		D (50%) NMT 75 microns	26µm
		D (90%) NMT 250 microns	73µm

MANUFACTURING DATE	September 2021		
RETEST DATE	March 2023		
ANALYSES	Date : October, 15 <sup>th</sup> 2021 By : A.MANCEAU/A.NEVEU/C.COUPÉAU/LABSERVICE/ACM Pharma		
CONCLUSION	<b>COMPLIANT WITH CURRENT SPECIFICATION</b>		
Written by : Isabelle Dorin		Reviewed by : Sophie GEORGIN	
Date : 18/10/2021	Visa : 	Date : 05/11/21	Visa : 