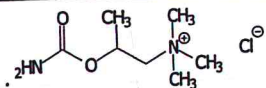


# BETHANECHOL CHLORIDE USP CERTIFICATE OF ANALYSIS

V01

SPE n° CQ - 088, vs 14



Cl<sup>-</sup>

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-111

| TESTS      | METHODS                      | SPECIFICATIONS           | RESULTS                  |
|------------|------------------------------|--------------------------|--------------------------|
| CHARACTERS | Visually<br>MOD n°: CQ - 673 | White crystalline powder | White crystalline powder |

## IDENTIFICATION

|                                   |                                |                                                                                                                                    |          |
|-----------------------------------|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------|----------|
| A: Infrared absorption            | USP (197M)<br>MOD n°: CQ - 673 | Conform to spectrum of <i>Bethanechol chloride reference standard</i>                                                              | Complies |
| B: Chromatographic retention time | USP <621><br>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 | Complies |
| C: Chloride                       | USP (191)<br>MOD n°: CQ - 673  | A solution of it responds to the tests                                                                                             | Complies |

## TESTS

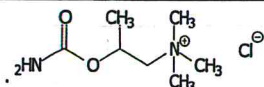
|                     |                               |                                                                                                                |          |
|---------------------|-------------------------------|----------------------------------------------------------------------------------------------------------------|----------|
| pH                  | USP (791)<br>MOD n°: CQ - 673 | 5.5 - 6.5                                                                                                      | 5.8      |
| Loss on drying      | USP (731)<br>MOD n°: CQ - 673 | NMT 1.0%                                                                                                       | 0.4%     |
| Residue on Ignition | USP (281)<br>MOD n°: CQ - 673 | NMT 0.1%                                                                                                       | 0.0%     |
| Heavy metals        | USP (231)<br>MOD n°: CQ - 673 | NMT 0.003%                                                                                                     | Complies |
| Chloride content    | USP<br>MOD n°: CQ - 673       | 17.70% - 18.30%                                                                                                | 18.09%   |
| ASSAY               | USP <621><br>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 | 98.0%    |

|                             |                                                                                            |
|-----------------------------|--------------------------------------------------------------------------------------------|
| Written by : S. GEBICZYNSKI | Reviewed by : S. GEORGIN                                                                   |
| Date : 05/03/17             | Visa :  |
| Date : 06/03/17             | Visa :  |

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## BATCH N° BTHA-111

| TESTS                         | METHODS                                      | SPECIFICATIONS                                 | RESULTS |
|-------------------------------|----------------------------------------------|------------------------------------------------|---------|
| Impurities/Related substances | USP <621><br>Seratec SOP<br>MOD n°: CQ - 673 | Desacetyl methacholine : NMT 0.2%              | ND      |
|                               |                                              | Any individual unspecified impurity : NMT 0.1% | ND      |
|                               |                                              | Ammonium chloride: NMT 0.2%                    | ND      |
| Residual Solvents             | USP <621><br>Seratec SOP<br>MOD n°: CQ - 673 | Total Impurities: NMT 0.6%                     | ND      |
|                               |                                              | Triethylamine ≤ 38 ppm                         | ND      |
|                               |                                              | Chloroforme ≤ 60 ppm                           | ND      |
|                               |                                              | Methanol ≤ 300 ppm                             | ND      |
|                               |                                              | Ethanol ≤ 500 ppm                              | 211 ppm |
|                               |                                              | Acetone ≤ 50 ppm                               | ND      |
| Particle Size Distribution    | Seratec SOP<br>MOD n°: CQ - 673              | Isopropanol ≤ 1000 ppm                         | ND      |
|                               |                                              | Acetonitrile ≤ 250 ppm                         | ND      |
|                               |                                              | D (10%) NMT 10 microns                         | 4 µm    |
|                               |                                              | D (50%) NMT 75 microns                         | 16 µm   |
|                               |                                              | D (90%) NMT 250 microns                        | 35 µm   |

ND : Not detected

|                    |             |
|--------------------|-------------|
| MANUFACTURING DATE | March 2017  |
| RETEST DATE        | August 2018 |

|            |                                           |                             |
|------------|-------------------------------------------|-----------------------------|
| ANALYSES   | Date : March 05 <sup>th</sup> , 2017      | By : C. COUPEAU & S. MOREAU |
| CONCLUSION | Compliant with current USP specifications |                             |

|                 |              |                 |            |
|-----------------|--------------|-----------------|------------|
| Written by :    | S. GEBZYNSKI | Reviewed by :   | S. GEORGIN |
| Date : 05/03/17 | Visa :       | Date : 06/03/17 | Visa :     |