

## CERTIFICATE OF ANALYSIS

Material No: **701551**  
Name: **Trospium chloride**  
Quality: **US NDC n° 610100, EINECS n° 233-875-4**  
We hereby certify that the batches of the product has been manufactured in full compliance with the cGMP regulation.  
Lot No: **20416018** Manufacturing date: **24-Oct-2020**  
CAS No. **10405-02-4** Retest date: **24-Oct-2025**  
Formula: **-** Specification date: **11-Sep-2020**  
Molecular Weight: **-**

| Test                 | Method          | Specification                                                           | Result   |
|----------------------|-----------------|-------------------------------------------------------------------------|----------|
| DESCRIPTION          | 10629__DEF00100 | white to off white crystalline powder (According to Ph. Eur.)           | Complies |
| IDENTIFICATION IR    | 10629__DEF00400 | complies with reference (According to Ph. Eur. and USP)                 | Complies |
| IDENTIF. CHLORIDES   | 10629__DEF00500 | complies (According to Ph. Eur. and USP)                                | Complies |
| IDENTIFICATION HPLC  | 10629__DEF06100 | RT complies with reference (according to USP)                           | Complies |
| DSC                  | 10629__DEF15800 | single endotherm between 100 and 280 °C                                 | Complies |
|                      | 10629__DEF11100 | Endotherm: 270 - 278 °C                                                 | 274 °C   |
| CLARITY OF SOLUTION  | 10629__DEF00700 | clear (According to Ph. Eur.)                                           | Complies |
| COLOUR OF SOLUTION   | 10629__DEF00800 | not more colored than B7 (According to Ph. Eur.)                        | Complies |
| pH                   | 10629__DEF01000 | 5.0 - 7.0 (According to Ph. Eur.)                                       | 5.7      |
| SULPHATED ASH        | 10629__DEF01400 | max. 0.1 % (According to Ph. Eur. and USP)                              | 0.0 %    |
| LOSS ON DRYING       | 10629__DEF01200 | max. 0.5 % (According to Ph. Eur. and USP)                              | 0.1 %    |
| ASSAY (AgNO3)        | 10629__DEF16000 | 99.0 - 101.0 % (on the dried substance)                                 | 100.0 %  |
| TLC                  | 10629__DEF03600 | Trospiro (Impurity C): max. 0.1 % (According to Ph. Eur.)               | Complies |
| ASSAY (HPLC)         | 10629__DEF03400 | 98.0 - 102.0 % (dried basis)                                            | 99.7 %   |
| IMPURITIES (HPLC)    | 10629__DEF07300 | Benzilic acid (Impurity A): max. 0.15 % (According to Ph. Eur. and USP) | <0.05 %  |
|                      | 10629__DEF07300 | Impurity B: max. 0.15 % (According to Ph. Eur. and USP)                 | <0.05 %  |
|                      | 10629__DEF07300 | any unspecified impurity: max. 0.10 % (According to Ph. Eur. and USP)   | <0.05 %  |
|                      | 10629__DEF07300 | total of unspecified impurities: max. 0.2 %                             | 0.0 %    |
|                      | 10629__DEF07300 | total impurities: max. 0.5 % (According to Ph. Eur. and USP)            | 0.0 %    |
| IMPURITIES (HPLC) II | 10629__DEF07900 | DMF: max. 880 ppm                                                       | 111 ppm  |
| PARTICLES SIZE       | 10629__DEF02500 | D 90 %: for information                                                 | 74 µm    |
|                      | 10629__DEF02500 | D 50 %: for information                                                 | 20 µm    |
|                      | 10629__DEF02500 | D (4,3): for information                                                | 31 µm    |

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| IMPURITIES (HPLC) IV | 10629__DEF38000 | Trospiro (Impurity C): max. 0.1 %<br>(According to USP) | 0.1 %  |

Release comment: **meets specification**

Released On: **24-Nov-2020 08:36 (UTC+01:00)**  
on behalf of Siegfried St. Vulbas SAS

Released By: **Charpentier Léa**  
**Q-UNIT**

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