



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 222542**

|                   |   |
|-------------------|---|
| Product:          | GLYCOPYRROLATE                                    |
| Lot:              | 222542  |
| Expiry date:      | 06/01/2027  |
| Reference:        | Cumple PhEur10.7                                  |
| Synonyms:         | Glicopirronio bromuro.                            |
| Formula:          | C <sub>19</sub> H <sub>28</sub> BrNO <sub>3</sub> |
| Molecular weight: | 398.34 g/mol                                      |

| Assay                         | Result        | Specification    |   |
|-------------------------------|---------------|------------------|---|
| Identification                | Conform (A,B) | Test PhEur (A,B) |   |
| Organoleptic properties       | Conform       | PhEur            |   |
| Appearance of solution        | Conform       |                  |   |
| Acidity or alkalinity         | Conform       | Test PhEur       |   |
| Loss on drying (3h, 105°C)    | 0,04 %        | <= 0,5 %         |   |
| Sulphated ashes               | 0,00 %        | <= 0,1%          |   |
| Related substances (HPLC)     | Conform       | Test PhEur       |   |
| Impurity N                    | < 0,2 %       | <= 0,2%          | # |
| Assay                         | 100,1 %       | 99,0-101,0%      |   |
| Impurity E                    | <= 0,05 %     | <= 0,2 %         |   |
| Impurity I                    | <= 0,05 %     | <= 0,3 %         |   |
| Unspecified Impurities        | <= 0,05 %     | <= 0,10 %        |   |
| Total impurities              | <= 0,05 %     | <= 0,5 %         |   |
| Residual solvent: Isopropanol | < 3000 ppm    | <= 3000 ppm      | # |
| Residual solvent: Heptane     | <1000 ppm     | <= 1000 ppm      | # |
| Residual solvent: Methanol    | <1000 ppm     | <= 1000 ppm      | # |

Organoleptic characteristics: White or almost white crystalline powder. Freely soluble in water, soluble in ethanol 96%, very slightly soluble in methylene chloride

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 30/05/2022

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01007 PCAS FINLAND OY

Manufacturer batch: 22000309

| Product | Name           | Capacity | Batch      |
|---------|----------------|----------|------------|
| 1112000 | GLICOPIRROLATO | 1 g      | 222542-D-1 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.  
Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer  
(=) UE certificate

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