



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 233770

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|--------------------|---|
| Product: | GLYCOPYRROLATE |
| Lot: | 233770 |
| Expiry date: | 30/08/2028 |
| Reference: | Cumple PhEur11.2 |
| Synonyms: | Glicopirronio bromuro. |
| Formule: | C ₁₉ H ₂₈ BrNO ₃ |
| Poids moléculaire: | 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) | 0,00 % | <= 0,5 % | |
| Sulphated ashes | <= 0,1 % | <= 0,1% | = |
| Related substances (HPLC) | Conform | Test PhEur | = |
| Impurity N | < 0,2 % | <= 0,2% | = |
| Assay | 99,2 % | 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: 21/11/2023

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F01007 PCAS FINLAND OY

Manufacturer batch: 23010973

| | | | |
|---------|----------------|----------|------------|
| Produit | Nom | Capacité | Lot |
| 1112000 | GLICOPIRROLATO | 1 g | 233770-D-1 |

| | | | |
|---------|---------------------------------|-----|------------|
| 1112000 | GLICOPIRROLATO | 1 g | 233770-D-3 |
| 1112000 | GLICOPIRROLATO | 1 g | 233770-D-5 |
| 1112000 | GLICOPIRROLATO | 1 g | 233770-D-6 |
| 1370201 | GLICOPIRROLATO (FLB) (INACTIVO) | 1 g | 233770-D-2 |
| 1370201 | GLICOPIRROLATO (FLB) (INACTIVO) | 1 g | 233770-D-4 |

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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