



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241267

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|--------------------|--|
| Product: | AMBROXOL HYDROCHLORIDE |
| Lot: | 241267 |
| Expiry date: | 30/10/2029 |
| Reference: | Cumple PhEur11.5 |
| Synonyms: | |
| Formule: | C ₁₃ H ₁₉ Br ₂ CIN ₂ O |
| Poids moléculaire: | 414.6 g/mol |

| Assay | Result | Specification | |
|---------------------------|---------------|------------------|---|
| Identification | Conform (B,D) | Test PhEur (B,D) | |
| Organoleptic properties | Conform | | |
| Related substances (HPLC) | Conform | Test PhEur | = |
| Elemental impurities | Conform | Test PhEur | # |
| Assay | 100,5 % | 99,0 - 101,0 % | |
| Sulphated ashes | 0,01 % | <= 0,1 % | = |
| Loss on drying | 0,05 % | <= 0,5 % | |
| Appearance of solution S | Conform | Test PhEur | = |
| pH | 4,9 | 4,5 - 6,0 | = |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | = |
| Total impurities | < 0,05 % | <= 0,3 % | = |
| Residual solvents | Conform | Test PhEur | # |

Organoleptic characteristics: White or yellowish, crystalline powder. Sparingly soluble in water, soluble in methanol, practically insoluble in methylene chloride.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 15/07/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00406 ERREGIERRE S.p.A.

Manufacturer batch: B230065

| Produit | Nom | Capacité | Lot |
|---------|-----------------------|----------|------------|
| 1100054 | AMBROXOL HIDROCLORURO | 100 g | 241267-J-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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