



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240015

| | |
|--------------------|---|
| Product: | PAPAVERINA HYDROCHLORIDE |
| Lot: | 240015 |
| Expiry date: | 30/08/2027 |
| Reference: | Cumple PhEur11.3 |
| Synonyms: | |
| Formule: | C ₂₀ H ₂₂ ClNO ₄ |
| Poids moléculaire: | 375,9 g/mol |

| Assay | Result | Specification | |
|------------------------------|--------------|---------------|---|
| Identification | Conform(A,D) | | |
| Organoleptic properties | Conform | | |
| Appearance of solution S | Conform | | |
| pH | 3,3 | 3,0 - 4,0 | |
| Related substances (HPLC) | Conform | | |
| Loss on drying | 0,01% | <= 0,5 % | |
| Sulphated ashes | 0,04% | <= 0,1 % | |
| Assay | 99,3% | 99,0-101,0% | |
| Individual impurities | < 0,05 % | <= 0,1 % | |
| Total impurities | < 0,05 % | <= 0,5 % | |
| Elemental impurities | Conform | Test PhEur | # |
| Residual solvent: Chloroform | < 60 ppm | <= 60 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Nitrosamine impurities | Conform | Test PhEur | # |

Organoleptic characteristics: White or almost white, crystalline powder, or white or almost white crystals.
Sparingly soluble in water, slightly soluble in ethanol (96 per cent).

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 25/01/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F01033 SYNNAT PHARMA PRIVATE LIMITED

Manufacturer batch: 64130922

| Produit | Nom | Capacité | Lot |
|---------|---|----------|------------|
| 1370257 | PAPAVERINA CLORHIDRATO (FLB) (INACTIVO) | 10 g | 240015-F-1 |
| 1370258 | PAPAVERINA CLORHIDRATO (FLB) (INACTIVO) | 50 g | 240015-I-1 |
| 1370259 | PAPAVERINA CLORHIDRATO (FLB) (INACTIVO) | 100 g | 240015-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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Date d'édition: 22/06/2026

