



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250042

| | |
|--------------------|---|
| Product: | ATROPINE SULPHATE |
| Lot: | 250042 |
| Expiry date: | 30/08/2028 |
| Reference: | Cumple PhEur11.6 |
| Synonyms: | |
| Formule: | (C ₁₇ H ₂₃ NO ₃) ₂ ·H ₂ SO ₄ ·H ₂ O |
| Poids moléculaire: | 694,84 g/mol |

| Assay | Result | Specification | |
|--------------------------------------|-----------------|----------------------|---|
| Identification | Conform (A,B,E) | Test PhEur (A,B,E) | |
| Organoleptic properties | Conform | PhEur | |
| pH aqueous solution 2% | 5,5 | 4,5 - 6,2 | |
| Optical rotation | -0,01° | (-0,5°)-(+0,05°) | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Moisture - K.F. (s/0,5g) | 3,1 % | 2,0-4,0% | |
| Sulphated ashes | 0,04 % | <= 0,1 % | |
| ASSAY (anhydrous vehicle PFP) | 100,1 % s.p.s. | 99,0 - 101,0% s.p.s. | |
| Impurity A | ND | <= 0,2 % | |
| Impurity B | < 0,05 % | <= 0,2 % | |
| Impurity C | ND | <= 0,2 % | |
| Impurity D | ND | <= 0,2 % | |
| Impurity E | ND | <= 0,3 % | |
| Impurity F | ND | <= 0,2 % | |
| Impurity G | ND | <= 0,2 % | |
| Impurity H | ND | <= 0,3 % | |
| Unspecified Impurities | ND | <= 0,10 % | |
| Total impurities | < 0,05 % | <= 0,5 % | |
| Residual solvent: methylene chloride | < 600 ppm | <= 600 ppm | # |
| Residual solvent: Isopropanol | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Acetonitrile | < 410 ppm | <= 410 ppm | # |

Organoleptic characteristics: White or almost white, crystalline powder or colourless crystals. Very soluble in water, freely soluble in ethanol 96%.

Conservation: In tightly closed containers. Protect form light and moisture.

Date of analysis: 29/01/2025

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00384 SAURAV CHEMICALS LIMITED

Manufacturer batch: ATS240004

| Produit | Nom | Capacité | Lot |
|---------|------------------------|----------|------------|
| 1104283 | ATROPINA SULFATO | 5 g | 250042-E-2 |
| 1370157 | ATROPINA SULFATO (FLB) | 5 g | 250042-E-1 |
| 1370157 | ATROPINA SULFATO (FLB) | 5 g | 250042-E-3 |

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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