



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 220381**

|                   |                         |
|-------------------|-------------------------|
| Product:          | EPHEDRINE HYDROCHLORIDE |
| Lot:              | 220381                  |
| Expiry date:      | 25/11/2026              |
| Reference:        | Cumple PhEur10.6        |
| Synonyms:         |                         |
| Formula:          | C10H16ClNO              |
| Molecular weight: | 201,7 g/mol             |

| Assay                              | Result        | Specification       |
|------------------------------------|---------------|---------------------|
| Identification                     | Conform (B,E) | Test PhEur (B,E)    |
| Organoleptic properties            | Conform       | Test PhEur          |
| Melting point (Mettler)            | 219 °C        | Approx. 219 °C      |
| Appearance of solution             | Conform       | Clear and colorless |
| Acidity or alkalinity              | Conform       | Test PhEur          |
| Specific rotation                  | -34,3°        | (-33,5°) - (-35,5°) |
| Related substances (HPLC)          | Conform       | Test PhEur          |
| Sulphates                          | < 100 ppm     | <= 100 ppm          |
| Loss on drying                     | 0,03 %        | <= 0,5 %            |
| Sulphated ashes                    | 0,00 %        | <= 0,1 %            |
| Assay                              | 99,3 %        | 99,0 - 101,0 %      |
| Impurity A                         | NDT           | <= 0,2 %            |
| Unspecified Impurities             | NDT           | <= 0,1 %            |
| Sum of impurities different from A | NDT           | <= 0,5 %            |
| Residual solvents                  | Conform       |                     |

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/03/2022

Judgement:  
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00368 SIEGFRIED PHARMACHEMICKALIEN MINDEN GmbH

Manufacturer batch: 21472094

| Product | Name                  | Capacity | Batch      |
|---------|-----------------------|----------|------------|
| 1100136 | EFEDRINA HIDROCLORURO | 1 kg     | 220381-P-1 |
| 1100136 | EFEDRINA HIDROCLORURO | 1 kg     | 220381-P-2 |

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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