



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242318

| | |
|-------------------|------------------|
| Product: | PRILOCAINE BASE |
| Lot: | 242318 |
| Expiry date: | 30/03/2029 |
| Reference: | Cumple PhEur11.5 |
| Synonyms: | |
| Formula: | C13H20N2O |
| Molecular weight: | 220,3 g/mol |

| Assay | Result | Specification | |
|--------------------------------------|------------|---------------|---|
| Identification | Conform | Test PhEur | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of solution | Conform | Test PhEur | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Elemental impurities | Conform | Test PhEur | # |
| Moisture - K.F. | 0,04 % | <= 0,5 % | |
| Sulphated ashes | 0,04 % | <= 0,1 % | |
| Assay | 100,2 % | 99,0-101,0% | |
| Impurity B | 22 ppm | <= 100 ppm | |
| Impurity G | < 0,05 % | <= 0,15 % | |
| Unspecified Impurities | 0,08 % | <= 0,10 % | |
| Total impurities | 0,08 % | <= 0,2 % | |
| Residual solvent: methylene chloride | < 600 ppm | <= 600 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Residual solvent: Petroleum ether | < 1200 ppm | <= 1200 ppm | # |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |

Organoleptic characteristics: Crystalline, white or almost white powder. Slightly soluble in water, very soluble in acetone and 96% ethanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 19/12/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00020 GUFIC BIOCIENCES LIMITED

Manufacturer batch: AE240117A

| Product | Name | Capacity | Batch |
|---------|-----------------|----------|------------|
| 1166848 | PRILOCAINA BASE | 250 g | 242318-N-1 |

| | | | |
|---------|-----------------|-------|------------|
| 1166848 | PRILOCAINA BASE | 250 g | 242318-N-2 |
| 1166849 | PRILOCAINA BASE | 1 kg | 242318-P-1 |
| 1166849 | PRILOCAINA BASE | 1 kg | 242318-P-2 |
| 1166851 | PRILOCAINA BASE | 25 g | 242318-G-1 |
| 1166860 | PRILOCAINA BASE | 5 kg | 242318-Q-1 |
| 1166860 | PRILOCAINA BASE | 5 kg | 242318-Q-2 |
| 1200271 | PRILOCAINA BASE | 100 g | 242318-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

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

Date of edition: 03/04/2026

