



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240561

| | |
|-------------------|---|
| Product: | LIDOCAINE HYDROCHLORIDE |
| Lot: | 240561 |
| Expiry date: | 30/12/2027 |
| Reference: | Cumple PhEur11.3 |
| Synonyms: | Lignocaina clorhidrato monohidrato. |
| Formula: | C ₁₄ H ₂₃ CIN ₂ O·H ₂ O |
| Molecular weight: | 288,8 g/mol |

| Assay | Result | Specification | |
|--|---------------|---------------------|---|
| Identification | Conform (B,D) | Test PhEur (B,D) | |
| Organoleptic properties | Conform | PhEur | |
| Appearance of the S solution (5% acq.) | Conform | Clear and colorless | |
| pH of aqueous solution 0,5% | 5,4 | 4,0-5,5 | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Moisture - K.F. | 6,2 % | 5,5 - 7,0 % | |
| Sulphated ashes | 0,01 % | <= 0,1% | |
| Assay | 99,6 % | 99,0-101,0% | |
| Impurity A | < 0,01 % | <= 0,01 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | < 0,05 % | <= 0,5 % | |
| Residual solvent: acetone | < 5000 ppm | <= 5000 ppm | # |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Elemental impurities | Conform | Test PhEur | # |

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

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 21/03/2024

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00340 SWATI SPENTOSE PRIVATE LIMITED (UNIT-I)

Manufacturer batch: LDH-723005

| Product | Name | Capacity | Batch |
|---------|-----------------------|----------|------------|
| 1157042 | LIDOCAINA CLORHIDRATO | 25 g | 240561-G-1 |
| 1157042 | LIDOCAINA CLORHIDRATO | 25 g | 240561-G-2 |
| 1157042 | LIDOCAINA CLORHIDRATO | 25 g | 240561-G-3 |

| | | | |
|---------|-----------------------|-------|------------|
| 1157044 | LIDOCAINA CLORHIDRATO | 100 g | 240561-J-1 |
| 1157044 | LIDOCAINA CLORHIDRATO | 100 g | 240561-J-2 |
| 1157044 | LIDOCAINA CLORHIDRATO | 100 g | 240561-J-3 |
| 1157047 | LIDOCAINA CLORHIDRATO | 1 kg | 240561-P-1 |
| 1157047 | LIDOCAINA CLORHIDRATO | 1 kg | 240561-P-2 |
| 1157047 | LIDOCAINA CLORHIDRATO | 1 kg | 240561-P-3 |
| 1200191 | LIDOCAINA CLORHIDRATO | 250 g | 240561-N-1 |
| 1200191 | LIDOCAINA CLORHIDRATO | 250 g | 240561-N-2 |
| 1200191 | LIDOCAINA CLORHIDRATO | 250 g | 240561-N-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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Date of edition: 05/04/2026

