



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224531

| | |
|-------------------|--|
| Product: | LIDOCAINE BASE |
| Lot: | 224531 |
| Expiry date: | 30/04/2027 |
| Reference: | Cumple PhEur10.8 |
| Synonyms: | Lignocaína. |
| Formula: | C ₁₄ H ₂₂ N ₂ O |
| Molecular weight: | 234,3 g/mol |

| Assay | Result | Specification | |
|---------------------------|-------------|----------------|---|
| Identification | Conform (A) | Test PhEur (A) | |
| Organoleptic properties | Conform | PhEur | |
| Chlorides | < 35 ppm | <= 35 ppm | |
| Sulphates | < 0,1 % | <= 0,1% | |
| Related substances (HPLC) | Conform | Test PhEur | |
| Moisture - K.F. | 0,09 % | <= 1,0 % | |
| Sulphated ashes | 0,05 % | <= 0,1% | |
| Assay | 100,3 % | 99,0-101,0% | |
| Impurity A | < 0,01 % | <= 0,01 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | < 0,05 % | <= 0,5 % | |
| Residual solvent: Toluene | < 890 ppm | <= 890 ppm | # |
| Elemental impurities | Conform | Test PhEur | # |

Organoleptic characteristics: White or almost white, crystalline powder. Practically insoluble in water, very soluble in ethanol (96 per cent) and in methylene chloride.

Conservation: In tightly closed containers. PROTECT FROM LIGHT.

Date of analysis: 08/09/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

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

Manufacturer batch: LDB-722018

| Product | Name | Capacity | Batch |
|---------|----------------|----------|------------|
| 1157001 | LIDOCAINA BASE | 25 g | 224531-G-1 |
| 1157003 | LIDOCAINA BASE | 100 g | 224531-J-1 |
| 1157003 | LIDOCAINA BASE | 100 g | 224531-J-2 |
| 1157004 | LIDOCAINA BASE | 250 g | 224531-N-1 |

| | | | |
|---------|----------------------|-------|------------|
| 1157004 | LIDOCAINA BASE | 250 g | 224531-N-2 |
| 1157005 | LIDOCAINA BASE | 1 kg | 224531-P-2 |
| 1157005 | LIDOCAINA BASE | 1 kg | 224531-P-3 |
| 1157006 | LIDOCAINA BASE | 5 kg | 224531-Q-1 |
| 1157006 | LIDOCAINA BASE | 5 kg | 224531-Q-2 |
| 1370213 | LIDOCAINA BASE (FLB) | 100 g | 224531-J-3 |
| 1370214 | LIDOCAINA BASE (FLB) | 1 kg | 224531-P-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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