

**LIDOCAINA BASE (EUR. PH.)**

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|--------------------------------|--------------------------------|---------------------|
| PRODUCT CODE: 1201 | CAS Nº: 137-58-6 | ANALYSIS Nº: 266/25 |
| MANUFACTURER BATCH: LDB/125010 | CERTIFICATE ID: 47.907 | |
| SUPPLIER BATCH: ---- | MANUFACTURING DATE: 01/03/2025 | |
| METAPH BATCH: 0070825 | EXPIRY DATE: 28/02/2030 | |

| ATTRIBUTES | SHOULD BE | IS |
|------------------------|--|--------------------------|
| Appearance | White or almost white, crystalline powder | White crystalline powder |
| Solubility | Practically insoluble in water, very soluble in ethanol (96 %) and in methylene chloride | Complies (*) |
| Identification A | Complies | Complies |
| Related substances | | |
| Impurity A | =< 0.01 % | Not Detected |
| Unspecified impurities | =< 0.10 % | < 0.05 % |
| Total impurities | =< 0.5 % | < 0.05 % |
| Chlorides | =< 35 ppm | < 35 ppm |
| Sulfates | =< 0.1 % | < 0.1 % |
| Water | =< 1.0 % | 0.06 % |
| Sulfated ash | =< 0.1 % | 0.07 % |
| Assay | 99.0 - 101.0 % | 99.7 % |

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Lidocaine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed in a well-ventilated place. Protect from light.

Analysis date: 10/11/2025

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000569

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