

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

PRODUCT CODE: 1201	CAS Nº: 137-58-6	ANALYSIS Nº: 016/24
MANUFACTURER BATCH: LDB/723003	CERTIFICATE ID: 40.993	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/01/2023	
METAPH BATCH: 0030224	EXPIRY DATE: 31/12/2027	

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 %	0.3 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	99.0 - 101.0 %	99.6 %

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

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

(\*) 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: 19/02/2024  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000569  
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