METAPHARMACEUTICAL IND SL
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LIDOCAINA BASE (EUR. PH.)

PRODUCT CODE: 1201	CAS Nº: 137-58-6	ANALYSIS Nº: 249/24	
MANUFACTURER BATCH:	LDB/723032	CERTIFICATE ID:	43.669
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/10/2023
METAPH BATCH:	0011024	EXPIRY DATE:	30/09/2028

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 %	0.08 %
Assay	99.0 - 101.0 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents 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.

(*) 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: 21/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000569