

**LIDOCAINA HCL MONOHIDRATO (EUR. PH.)**

PRODUCT CODE: 1202	CAS Nº: 6108-05-0	ANALYSIS Nº: 040/24
MANUFACTURER BATCH: MC/LH/0005/24	CERTIFICATE ID: 41.260	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/01/2024	
METAPH BATCH: 0270224	EXPIRY DATE: 30/12/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 %)	Complies (*)
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	4.0 - 5.5	5.0
Related substances		
Impurity A	=< 0.01 %	0.004 %
Unspecified impurities	=< 0.1 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Water	5.5 - 7.0 %	6.4 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	99.0 - 101.0 %	100.7 %

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 Hydrochloride Monohydrate 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 tightly closed and in a dry and cool place, and protected from the light.

Analysis date: 06/03/2024
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000825
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