

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

PRODUCT CODE: 1202	CAS Nº: 6108-05-0	ANALYSIS Nº: 134/22
MANUFACTURER BATCH: LDH/721011	CERTIFICATE ID: 35.039	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/06/2021	
METAPH BATCH: 0180522	EXPIRY DATE: 01/05/2026	

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	Complies
pH	4.0 - 5.5	4.8
Related substances		
Impurity A	=< 0.01 %	0.0004 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Water	5.5 - 7.0 %	6.3 %
Sulfated ash	=< 0.1 %	0.10 %
Assay	99.0 - 101.0 %	100.4 %
Residual solvents		(*) (**)
Acetone	=< 5000 ppm	692 ppm
Toluene	=< 890 ppm	0.50 ppm

**COMPLIES WITH**

European Pharmacopoeia 10.0

**REMARKS**

Lidocaine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

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

(\*\*) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 21/06/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000569

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