

LIDOCAINA HCL MONOHIDRATO (EUR. PH.)

PRODUCT CODE: 1202	CAS Nº: 6108-05-0	ANALYSIS Nº: 091/22
MANUFACTURER BATCH: LDH/120084	CERTIFICATE ID: 34.491	
SUPPLIER BATCH: 214797	MANUFACTURING DATE: 01/11/2020	
METAPH BATCH: 0310322	EXPIRY DATE: 01/10/2025	

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	5.4
Related substances		
Impurity A	=< 0.01 %	0.001 %
Unspecified impurities	=< 0.10 %	=< 0.05 %
Total impurities	=< 0.5 %	=< 0.05 %
Water	5.5 - 7.0 %	6.5 %
Sulfated ash	=< 0.1 %	0.08 % (*)
Assay	99.0 - 101.0 %	100.5 % (*)
Residual solvents		(**)
Acetone	=< 5000 ppm	1410 ppm
Toluene	=< 890 ppm	< LoD

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Product fully analyzed inside the EU.

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 controlled by Metapharmaceutical Industrial SL.

(**) 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: 12/04/2022
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000569
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 GUJARAT(India)

