



## TECHNICAL DATA SHEET

1202-TDS-ENG-2023

LIDOCAINA HCL MONOHIDRATO (PH. EUR.)		
DESCRIPTION DCI: LIDOCAINE HYDROCHLORIDE		DESCRIPTION DOE: LIDOCAINA HIDROCLORURO
CAS N°: 6108-05-0	EC N°: 200-803-8	AEMPS CODE: 48CH
MOL. WEIGHT: 288.80	MOL. FORMULA: C <sub>14</sub> H <sub>23</sub> ClN <sub>2</sub> O·H <sub>2</sub> O	ARTICLE CODE: 1202

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Very soluble in water, freely soluble in ethanol (96 %)
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and colourless
pH	4.0 - 5.5
Related substances	
Impurity A	= < 0.01 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Water	5.5 - 7.0 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

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

### REMARKS

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.

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.