



TECHNICAL DATA SHEET

1201-TDS-ENG-2023

LIDOCAINA BASE (PH.EUR)		
DESCRIPTION DCI: LIDOCAINE		DESCRIPTION DOE: LIDOCAINA
CAS N°: 137-58-6	EC N°: 205-302-8	AEMPS CODE: 48A
MOL. WEIGHT: 234.33	MOL. FORMULA: C14H22N2O	ARTICLE CODE: 1201

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Practically insoluble in water, very soluble in ethanol (96 %) and in methylene chloride
Identification A	Complies
Related substances	
Impurity A	= < 0.01 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Chlorides	= < 35 ppm
Sulfates	= < 0.1 %
Water	= < 1.0 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed in a well-ventilated place. Protect from light.

REMARKS

Lidocaine 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.