



## TECHNICAL DATA SHEET

151390-TDS-ENG-2024

MEPIVACAINA HCL (EUR. PH.)		
DESCRIPTION DCI: MEPIVACAINE HYDROCHLORIDE		DESCRIPTION DOE: MEPIVACAINA HIDROCLORURO
CAS Nº: 1722-62-9	EC Nº: 217-023-9	AEMPS CODE: 1909CH
MOL. WEIGHT: 282,81	MOL. FORMULA: C15H22N2OHCl	ARTICLE CODE: 151390

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water and in ethanol (96 %), very slightly soluble in methylene chloride
Melting point	About 260 °C, with decomposition
Identification A	Complies
Identification C	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. B7
pH	4.0 - 5.0
Optical rotation	-0.10° / +0.10°
Related substances	
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Impurity A	=< 20 ppm
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Residual solvents [In-house]	
Acetone	=< 1000 ppm

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store in a well-ventilated place. Store at room temperature. Keep container closed when not in use.

### REMARKS

It shows polymorphism.

Mepivacaine Hydrochloride 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



## TECHNICAL DATA SHEET

151390-TDS-ENG-2024

<b>MEPIVACAINA HCL (EUR. PH.)</b>		
DESCRIPTION DCI: MEPIVACAINE HYDROCHLORIDE		DESCRIPTION DOE: MEPIVACAINA HIDROCLORURO
CAS N°: 1722-62-9	EC N°: 217-023-9	AEMPS CODE: 1909CH
MOL. WEIGHT: 282,81	MOL. FORMULA: C15H22N2OHCl	ARTICLE CODE: 151390

product before use.