METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1494-TDS-ENG-2023

PRILOCAINA BASE (PH.EUR)		
DESCRIPTION DCI: PRILOCAINE	DESCRIPTION DOE: PRILOCAINA	
CAS Nº: 721-50-6	EC Nº: 211-957-0	AEMPS CODE: 2393A
MOL. WEIGHT: 220.30	MOL. FORMULA: C13H20N2O	ARTICLE CODE: 1494

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water, very soluble in acetone and in ethanol (96 %)
Identification	Complies
Appearance of solution	Clear and colourless
Related substances	
Impurity B	=< 100 ppm
Impurity G	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Water	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %
Residual solvents [In-house]	
Methylene Chloride	=< 600 ppm
Toluene	=< 890 ppm
Petroleum ether	=< 1200 ppm
Acetone	=< 5000 ppm

COMPLIES WITH

European Pharmacopoiea 11.0

STORAGE

Keep the containers tightly closed. Store in a cool, dry and well-ventilated place.

REMARKS

Prilocaine is subjected to the requirements of the ICH Q3D "Elemental Impurities" 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, 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.