



TECHNICAL DATA SHEET

1703-TDS-ENG-2023

TETRACAINA HCl (Pantocaina)(PH.EUR)		
DESCRIPTION DCI: TETRACAINE HYDROCHLORIDE		DESCRIPTION DOE: TETRACAINA HIDROCLORURO
CAS Nº: 136-47-0	EC Nº: 205-248-5	AEMPS CODE: 3255CH
MOL. WEIGHT: 300.83	MOL. FORMULA: C ₁₅ H ₂₄ N ₂ O ₂ ·HCl	ARTICLE CODE: 1703

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, slightly hygroscopic, crystalline powder
Solubility	Freely soluble in water, soluble in ethanol (96 %)
Melting range	It melts at about 148 °C or it may occur in either of 2 other crystalline forms which melt respectively at about 134 °C and 139 °C. Mixtures of these forms melt within the range 134 °C to 147 °C.
Identification A	Complies
Identification D	Complies
Appearance of solution	Clear and colourless
pH	4.5 - 6.5
Related substances	
Impurity A	=< 0.05 %
Impurity B	=< 0.1 %
Impurity C	=< 0.1 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 % - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Tetracaine 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 product before use.