



TECHNICAL DATA SHEET

001996-TDS-ENG-2025

ARTICAINE HCL (EUR. PH.)		
DESCRIPTION DCI: ARTICAINE HYDOCHLORIDE		DESCRIPTION DOE: ARTICAINE HIDRCLORURO
CAS Nº: 23964-57-0	EC Nº: 245-957-7	AEMPS CODE: 2538CH
MOL. WEIGHT: 320,84	MOL. FORMULA: C ₁₃ H ₂₀ N ₂ O ₃ S·HCl	ARTICLE CODE: 001996

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water and in ethanol (96 %)
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. BY6
pH	4.2 - 5.2
Related substances	
Impurity A	=< 0.2 %
Unspecified impurities	=< 0.10 %
Sum of impurities other than A	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

REMARKS

Articaine 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.