

TECHNICAL DATA SHEET

1344-TDS-ENG-2026

PROCAINA HCL (EUR. PH.)		
DESCRIPTION DCI: PROCAINE HYDROCHLORIDE		DESCRIPTION DOE: PROCAINA HIDROCLORURO
CAS Nº: 51-05-8	EC Nº: 200-077-2	AEMPS CODE: 988CH
MOL. WEIGHT: 272.75	MOL. FORMULA: C13H20N2O2·HCl	ARTICLE CODE: 1344

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Very soluble in water, soluble in ethanol (96 %), practically insoluble in heptane
Identification A	Complies
Identification B	Complies
Identification D	Complies
Melting point	154 - 158 °C
Appearance of solution	Clear and colourless
pH	5.0 - 6.5
Related substances	
Impurity F	=< 0.15 %
Impurity G	=< 0.15 %
Impurity H	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.2 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopeia 12.3

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Procaine 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.