



TECHNICAL DATA SHEET

1506-TDS-ENG-2023

PROPRANOLOL HCL (PH.EUR)		
DESCRIPTION DCI: PROPRANOLOL HYDROCHLORIDE		DESCRIPTION DOE: PROPRANOLOL HIDROCLORURO
CAS N°: 318-98-9	EC N°: 206-268-7	AEMPS CODE: 2218CH
MOL. WEIGHT: 295.81	MOL. FORMULA: C ₁₆ H ₂₁ NO ₂ ·HCl	ARTICLE CODE: 1506

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Soluble in water and in ethanol (96 %), practically insoluble in heptane
Identification B	Complies
Identification D	Complies
Appearance of solution	Complies
Acidity or alkalinity	Complies
Related substances	
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.2 %
Loss on drying	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container tightly closed. Store it in a fresh and well-ventilated place.

REMARKS

Propranolol 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.