

<b>PROPRANOLOL HCL (EUR. PH.)</b>			
PRODUCT CODE: 1506		CAS Nº: 318-98-9	ANALYSIS Nº: 077/22
MANUFACTURER BATCH:	102821029	CERTIFICATE ID:	34.403
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/05/2021
METAPH BATCH:	0220322	RETEST DATE:	31/05/2026

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Soluble in water and in ethanol (96 %), practically insoluble in heptane	Complies (*)
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Complies	Complies
Acidity or alkalinity	Complies	Complies
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.2 %	< 0.05 %
Loss on drying	=< 0.5 %	0.08 %
Sulfated ash	=< 0.1 %	< 0.01 %
Assay	99.0 - 101.0 %	100.9 %
Residual solvents		(*) (**)
Acetone	=< 500 ppm	< LoQ
Toluene	=< 300 ppm	< LoD
Particle size		(*)
53 µm	=> 50 %	53.4 %

#### COMPLIES WITH

European Pharmacopoeia 10.0

#### REMARKS

Propranolol Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(\*) Data adapted from the certificate of analysis of the manufacturer.

(\*\*) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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.

#### STORAGE

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

Analysis date: 01/06/2022  
 Signature: Ferran Gonzalez de Rivera Rier  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000512  
 COSMA SPA  
 Via Colleoni 15/17  
 24040 Ciserano  
 Bergamo(Itàlia)

