

PROPRANOLOL HCL (EUR. PH.)

PRODUCT CODE: 1506	CAS Nº: 318-98-9	ANALYSIS Nº: 110/23
MANUFACTURER BATCH: 22144PRRII	CERTIFICATE ID: 38.187	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/09/2022	
METAPH BATCH: 0240423	EXPIRY DATE: 30/08/2027	

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 %	0.06 %
Sulfated ash	=< 0.1 %	0.06 %
Assay	99.0 - 101.0 %	100.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

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.

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

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.

STORAGE

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

Analysis date: 01/06/2023
 Signature: Ferran Gonzalez de Rivera Rier
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000356
 IPCA LABORATORIES LIMITED
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 396195 Vapi
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