



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 224844

Product:	PROPRANOLOL HYDROCHLORIDE
Lot:	224844
Expiry date:	31/01/2027
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C ₁₆ H ₂₁ NO ₂ ·HCl
Molecular weight:	295,81 g/mol

Assay	Result	Specification	
Appearance of solution	Conform	Test PhEur	
Acidity or alkalinity	Conform		
Related substances (HPLC)	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,04 %	<= 0,5 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99,5 %	99,0-101,0%	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,2 %	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Identification	Conform (B,D)		
Residual solvent: Isopropanol	<= 5000 ppm	<= 5000 ppm	#
Organoleptic properties	Conform		

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/11/2022

Judgement:
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 22021PRR11

Product	Name	Capacity	Batch
1166982	PROPRANOLOL CLORHIDRATO	10 g	224844-F-1
1166982	PROPRANOLOL CLORHIDRATO	10 g	224844-F-2
1166982	PROPRANOLOL CLORHIDRATO	10 g	224844-F-3
1166982	PROPRANOLOL CLORHIDRATO	10 g	224844-F-4
1166982	PROPRANOLOL CLORHIDRATO	10 g	224844-F-5

1166984	PROPRANOLOL CLORHIDRATO	250 g	224844-N-1
1166984	PROPRANOLOL CLORHIDRATO	250 g	224844-N-2
1166984	PROPRANOLOL CLORHIDRATO	250 g	224844-N-3
1166984	PROPRANOLOL CLORHIDRATO	250 g	224844-N-4
1400142	PROPRANOLOL CLORHIDRATO	50 g	224844-I-1
1400142	PROPRANOLOL CLORHIDRATO	50 g	224844-I-2
1400142	PROPRANOLOL CLORHIDRATO	50 g	224844-I-3
1400142	PROPRANOLOL CLORHIDRATO	50 g	224844-I-4

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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Date of edition: 06/02/2025

