



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241688

Product:	ATENOLOL
Lot:	241688
Expiry date:	30/03/2029
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C ₁₄ H ₂₂ N ₂ O ₃
Molecular weight:	266,34 g/mol

Assay	Result	Specification	
Identification	Conform (B)		
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
Chlorides	< 0,1 %	<= 0,1%	
Related substances (HPLC)	Conform	Test PhEur	
Optical rotation	0,00 °	(-0,10°)-(+0,10°)	
Loss on drying	0,15 %	<= 0,5 %	
Sulphated ashes	0,08 %	<= 0,1%	
Assay	99,7 %	99,0-101,0%	
Impurity B	0,08 %	<= 0,2 %	
Impurity F	< 0,05 %	<= 0,15 %	
Impurity G	< 0,05 %	<= 0,15 %	
Impurity I	< 0,05 %	<= 0,15 %	
Impurity J	0,05 %	<= 0,15 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,13 %	<= 0,5 %	
Residual solvents	Conform	Test PhEur	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Tes PhEur	#

Organoleptic characteristics: White or almost white powder. Fairly soluble in water, soluble in ethanol, slightly soluble in methylene chloride.

Conservation: In tightly closed containers.

Date of analysis: 30/08/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00026 IPCA LABORATORIES LIMITED

Manufacturer batch: 24111A2BR11

Product	Name	Capacity	Batch
1104270	ATENOLOL	25 g	241688-G-2
1104270	ATENOLOL	25 g	241688-G-3
1104270	ATENOLOL	25 g	241688-G-5
1370234	ATENOLOL (FLB)	5 g	241688-E-1
1370234	ATENOLOL (FLB)	5 g	241688-E-4
1370235	ATENOLOL (FLB)	25 g	241688-G-1
1370235	ATENOLOL (FLB)	25 g	241688-G-4
1400017	ATENOLOL	5 g	241688-E-2
1400017	ATENOLOL	5 g	241688-E-3
1400017	ATENOLOL	5 g	241688-E-5

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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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