



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 242317

Product:	
Lot:	242317
Expiry date:	30/06/2027
Reference:	Cumple PhEur11.6
Synonyms:	
Formula:	C ₂₆ H ₄₀ O ₅
Molecular weight:	432,59 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform		
Moisture - K.F.	0,29 %	<= 0,50 %	
Specific rotation	+ 35,1	(+32,0) - (+37,0)	
Related substances (HPLC)	Conform	Test PhEur	
Impurity H	< 0,15 %	<= 0,15 %	
Elemental impurities	Conform	Test PhEur	#
Assay (HPLC)	99,3 %	94,0 - 102,0 %	
KEEP IN REFRIGERATOR OR FREEZER			
Impurity E	ND	<= 0,4 %	
Impurity F	0,13 %	<= 3,5 %	
Unspecified Impurities	0,06 %	<= 0,10 %	
Total impurities	0,16 %	<= 1,0 %	
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: tert-butyl methyl ether	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Hexane	< 290 ppm	<= 290 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Isopropyl ether	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Ethyl acetate	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: Dimethylformamide	< 880 ppm	<= 880 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics:

Conservation:

Date of analysis: 24/01/2025

Responsible: B. Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique
Manufacturer: F00174 NEWCHEM SPA
Manufacturer batch: NE1904

Product	Name	Capacity	Batch
1144288	LATANOPROST	500 mg	242317-C-1
1144289	LATANOPROST	100 mg	242317-A-1
1144290	LATANOPROST	5 mg	242317-AB-1

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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