



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 260257

Product:	
Lot:	260257
Expiry date:	30/06/2030
Reference:	Cumple PhEur12.1
Synonyms:	
Formule:	C26H40O5
Poids moléculaire:	432,59 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform		
Moisture - K.F.	0,28 %	<= 0,50 %	#
Specific rotation	+ 34,8	(+32,0) - (+37,0)	
Related substances (HPLC)	Conform	Test PhEur	
Impurity H (HPLC)	< 0,15 %	<= 0,15 %	
Elemental impurities	Conform	Test PhEur	#
Assay (HPLC)	97,5 %	94,0 - 102,0 %	
KEEP IN REFRIGERATOR OR FREEZER			
Impurity E	< 0,05 %	<= 0,4 %	
Impurity F	0,13 %	<= 3,5 %	
Unspecified Impurities	0,07 %	<= 0,10 %	
Total impurities	0,13 %	<= 1,0 %	
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: tert-butyl methyl ether	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Methanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: methylene chloride	< 600 ppm	<= 600 ppm	#
Residual solvent: Diethyl ether	< 1000 ppm	<= 1000 ppm	#
Residual solvent: Tetrahydrofuran	< 720 ppm	<= 720 ppm	#
Residual solvent: acetone	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform	Test PhEur	#
Residual solvent: Isopropyl acetate	< 1000 ppm	<= 1000 ppm	#
Residual solvent: Heptane	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Benzene	< 2 ppm	<= 2 ppm	#

Organoleptic characteristics:

Conservation:

Date of analysis: 27/02/2026

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00438 INDUSTRIALE CHIMICA S.R.L.

Manufacturer batch: PR251505

Produit	Nom	Capacité	Lot
1144290	LATANOPROST	5 mg	260257-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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