

LATANOPROST (EUR. PH.)							
PRODUCT CODE: 151384		CAS Nº: 130209-	82-4 A	ANALYSIS Nº: 053/23			
MANUFACTURER BATCH:	2210S003		CERTIFICATE ID:	37.564			
SUPPLIER BATCH:			MANUFACTURING DATE	31/10/2022			
МЕТАРН ВАТСН:	0250223		RETEST DATE:	31/10/2025			

ATTRIBUTES	SHOULD BE	IS	
Appearance	Clear, colourless or yellow, viscous, oily liquid	Clear, colourless, viscous, oily liquid	
Solubility	Practically insoluble in water, very soluble in acetonitrile, freely soluble in anhydrous ethanol	Complies (*)	
Identification A	Complies	Complies	
Identification B	Complies	Complies	
Specific optical rotation	+32.0 / +37.0	+34.2	
Related substances			
Impurity F	=< 3.5 %	0.25 %	
Impurity E	=< 0.4 %	< 0.05 %	
Unspecified impurities	=< 0.10 %	< 0.05 %	
Sum of impurities other than F	=< 1.0 %	0.10 %	
Impurity H	=< 0.15 %	Not Detected	
Water	=< 0.5 %	0.04 %	
Assay	94.0 - 102.0 %	101.5 %	
Residual solvents		(*) (**)	
Acetone	=< 1000 ppm	Not Detected	
Isopropyl alcohol	=< 1000 ppm	Not Detected	
Methylene Chloride	=< 600 ppm	Not Detected	
n-Heptane	=< 1000 ppm	< 1000 ppm	
Ethyl acetate	=< 1000 ppm	Not Detected	
Tetrahydrofuran	=< 200 ppm	Not Detected	
Toluene	=< 250 ppm	Not Detected	
tert-buylmethyleter	=< 300 ppm	Not Detected	
Dimethylformamide	=< 880 ppm	Not Detected	
Microbiological control		(*)	
TAMC	=< 2000 CFU/g	< 10 CFU/g	
TYMC	=< 200 CFU/g	< 10 CFU/g	
COMPLIES WITH			

European Pharmacopoeia 11.0

REMARKS

Latanoprost is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

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.

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

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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

Analysis date: 05/05/2023

Signature: Ferran Gonzalez de Rivera Rier

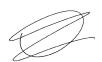
Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000463 CAYMAN PHARMA S.R.O.

Práce, 657

27711 NERATOVICE NERATOVICE(Txèquia)







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product before use.

STORAGE

Keep the container in tightlyclosed at 2 - 8 °C. Protect from light and heat.

Analysis date: 05/05/2023

Signature: Ferran Gonzalez de Rivera Rier

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