



## LATANOPROST (EUR. PH.)

PRODUCT CODE: 151384	CAS Nº: 130209-82-4	ANALYSIS Nº: 053/23
MANUFACTURER BATCH: 2210S003	CERTIFICATE ID: 37.564	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 31/10/2022	
METAPH BATCH: 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-butylmethyleter	=< 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)



## LATANOPROST (EUR. PH.)

PRODUCT CODE: 151384	CAS Nº: 130209-82-4	ANALYSIS Nº: 053/23
MANUFACTURER BATCH: 2210S003	CERTIFICATE ID: 37.564	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 31/10/2022	
METAPH BATCH: 0250223	RETEST DATE: 31/10/2025	

product before use.

### STORAGE

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

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.  
Práca, 657  
27711 NERATOVICE  
NERATOVICE(Txèquia)