

LATANOPROST (EUR. PH.)

PRODUCT CODE: 151384	CAS Nº: 130209-82-4	ANALYSIS Nº: 113/25
MANUFACTURER BATCH: NF0582	CERTIFICATE ID: 46.280	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 30/03/2025	
METAPH BATCH: 0310425	EXPIRY DATE: 30/03/2028	

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	+34.9
Related substances		
Impurity F	=< 3.5 %	< 0.05 %
Impurity E	=< 0.4 %	Not Detected
Unspecified impurities	=< 0.10 %	Not Detected
Sum of impurities other than F	=< 1.0 %	Not Detected
Impurity H	=< 0.15 %	Not Detected
Water	=< 0.5 %	0.36 %
Assay	94.0 - 102.0 %	100.2 %

COMPLIES WITH

European Pharmacopoeia 11.3

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Latanoprost is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

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

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.

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 product before use.

STORAGE

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

Analysis date: 20/06/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000294
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