

NEWCHEM

CERTIFICATE OF ANALYSIS LATANOPROST

Batch: **NF0582**

Manuf. date: **03/2025**

METAPHARMACEUTICAL

Expiration date: **03/2028**

N DE LOTE:

0310425

Alfandre
30/04/2025

Tests	Specifications	Results
GENERAL TESTS		
Appearance	Colorless or pale yellow oil	Complies
Identification IR	Positive	Positive
Identification HPLC	Positive	Positive
Water content	NMT 0,5 %	0,1 %
Specific rotation	+31° - +38° on anhydrous and solvent- free basis	+33 °
Specific optical rotation	+32.0° to +37.0° on anhydrous substance	34,4 °
Solubility	Complies	Complies
Sulphated ashes	NMT 0.50%	0,00 %
ASSAY		
HPLC Assay	98.0% - 102.0% on the anhydrous, solvent-free basis	98,9 %
RESIDUAL SOLVENTS		
Dichloromethane	NMT 600 ppm	N.D.
Isopropyl alcohol	NMT 2500 ppm	51 ppm
Tert-butyl-methyl-ether	NMT 500 ppm	N.D.
n-Hexane	NMT 150 ppm	N.D.
Isopropyl ether	NMT 5000 ppm	N.D.
Ethyl acetate	NMT 5000 ppm	3686 ppm
Tetrahydrofuran	NMT 500 ppm	N.D.
Dimethylformamide	NMT 100 ppm	N.D.
IMPURITIES		
Isopropyldiphenylpentanoate	NMT 0.10 %	N.Q.

Complies with cEP and cUSP

NEWCHEM declares that: this batch was produced under GMP condition; the documentation relevant to this process has been reviewed by the Quality Unit

Store at refrigerated conditions (+ 2 °C - + 8 °C)

Produced by **San Martino Siccomario site**

Verona

26/03/2025

Page 1 of 2

Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at:

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Company subject to direction and coordination of Zhejiang Xianju Pharmaceutical Co. Ltd.

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Tests	Specifications	Results
IMPURITIES		
15(S)-latanoprost	NMT 0.30%	N.Q.
5-trans-latanoprost	NMT 0.30%	0,07 %
Every single unknown impurity	NMT 0.10%	0,07 %
Total impurities	NMT 0.50 %	0,07 %
Related Compound E	NMT 0.10 %	N.D.

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