

NEWCHEM

CERTIFICATE OF ANALYSIS LATANOPROST

Batch: **NA2964**

Manuf. date: **09/2020**

Expiration date: **09/2023**

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 %	0.2 %
Specific rotation	+31° - +38° on anhydrous and solvent-free basis	+34°
Solubility	Complies	Complies
Sulphated ashes	NMT 0.50%	0.01 %
ASSAY		
Assay HPLC (USP)	98.0% - 102.0% on the anhydrous, solvent free basis	98.90 %
IMPURITIES		
Isopropylidiphenylpentanoate	NMT 0.10 %	N.G.
15(S)-latanoprost	NMT 0.30%	0.10 %
5-trans-latanoprost	NMT 0.30%	0.14 %
Every single unknown impurity	NMT 0.10%	0.07 %
Total Impurities	NMT 0.50 %	0.07 %
Related Compound E	NMT 0.10 %	0.01 %
RESIDUAL SOLVENTS		
Isopropyl alcohol	NMT 2500 ppm	N.D.
Tert-butyl-methyl-ether	NMT 500 ppm	N.D.
n-Hexane	NMT 150 ppm	N.D.
Dichloromethane	NMT 600 ppm	N.D.

Complies with 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

11/11/2020

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Approved by Qualified Person

NEWCHEM spa www.newchemspa.com

Sede legale/registered at: Via E. De Amicis 47 - 20123 Milano - Italy Tel. +39 02 581516 Info@newchemspa.it

Capitale sociale Euro 1.000.000 I.v. R.E.A. Mi n. 1559575 iscrizione registro Impresa MI - codice fiscale e partita IVA/vat 12437910156

Newchem Spa - Società soggetta a direzione e coordinamento di Zhejiang Xianju Pharmaceutical Co. Ltd.

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LATANOPROST

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RESIDUAL SOLVENTS		
Isopropyl ether	NMT 5000 ppm	N.D.
Ethyl acetate	NMT 5000 ppm	N.D.
Tetrahydrofuran	NMT 500 ppm	N.D.
Dimethylformamide	NMT 100 ppm	N.D.

Complies with cUSP

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