

lote 0400621

NEWCHEM

CERTIFICATE OF ANALYSIS LATANOPROST

Batch: **NA0711**

Manuf. date: **03/2020**

Expiration date: **03/2023**

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 %	0.1 %
Specific rotation	+31° - +38° on anhydrous and solvent- free basis	+33 °
Solubility	Complies	Complies
Sulphated ashes	NMT 0.50%	0.03 %
ASSAY		
Assay HPLC (USP)	98.0% - 102.0% on the anhydrous, solvent free basis	98.40 %
IMPURITIES		
Isopropyl diphenyl pentanoate	NMT 0.10 %	N.Q.
15(S)-latanoprost	NMT 0.30%	N.Q.
5-trans-latanoprost	NMT 0.30%	N.Q.
Every single unknown impurity	NMT 0.10%	0.08 %
Total impurities	NMT 0.50 %	0.08 %
Related Compound E	NMT 0.10 %	0.00 %
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.
Isopropyl ether	NMT 5000 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)

Producer: NEWCHEM S.p.A.

Via Parco del Ticino, 10 - 27028 San Martino Siccomario (PV) - Italy

NEWCHEM spa www.newchemspa.com

Sede legale/registered at: Via E. De Amicis 47 - 20123 Milano, Italy Tel. +39 02 581516  Approved by QA Manager

Verona: 0475/20780 Capitale sociale Euro 1.000.000 i.v. R.E.A. MI n. 1559575 Iscrizione registro imprese MI - codice fiscale e partita IVA/val 12437910156

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

Stabilimenti/factories:

Via Roveggia 47 - 37136 Verona - Italy Tel. +39 045 504922 Fax +39 045 8201568  info@newchemspa.it

Via Parco del Ticino 10 - 27028 San Martino Siccomario - Pavia - Italy Tel. +39 0382 521027 Fax +39 0382 490570  info@newchemspa.it

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RESIDUAL SOLVENTS		
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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