

NEWCHEM

CERTIFICATE OF ANALYSIS LATANOPROST

Batch: **NY0911**

Manuf. date: **04/2018**

Retest date: **04/2020**

Expiration date: **04/2021**

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	+31 °
Solubility	Complies	Complies
Sulphated ashes	NMT 0.50%	0.00 %
ASSAY		
Assay HPLC (USP)	98.0% - 102.0% on the anhydrous, solvent free basis	99.00 %
IMPURITIES		
Isopropylidiphenylpentanoate	NMT 0.10 %	N.Q.
15(S)-latanoprost	NMT 0.30%	0.08 %
5-trans-latanoprost	NMT 0.30%	0.11 %
Every single unknown impurity	NMT 0.10%	0.09 %
Total impurities	NMT 0.50 %	0.34 %
Related Compound E	NMT 0.10 %	0.01 %
RESIDUAL SOLVENTS		
Isopropyl alcohol	NMT 2500 ppm	93 ppm
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.
Ethyl acetate	NMT 5000 ppm	N.D.

Complies with cUSP

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

Producer: **NEWCHEM S.p.A.**

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

Verona, 27/04/2018

NEWCHEM spa www.newchemspa.com

Sede legale/registered at: via E. De Amicis 47 - 20123 Milano - Italy Tel. +39 02 581516 Fax +39 02 58151627 E-mail: info@newchemspa.it

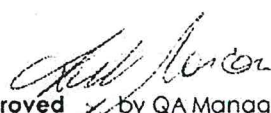
Capitale sociale Euro 1.000.000 i.v. R.E.A. MI n. 1559575 Iscrizione registro imprese MI, codice fiscale e partita IVA/ vat n. 12457070150

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RESIDUAL SOLVENTS		
Tetrahydrofuran	NMT 500 ppm	N.D.
Dimethylformamide	NMT 100 ppm	N.D.

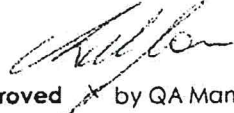
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