

16K: 0220420

NEWCHEM

CERTIFICATE OF ANALYSIS LATANOPROST

Batch: **NZ1706**

Manuf. date: **07/2019**

Expiration date: **07/2022**

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 %	0,3 %
Specific rotation	+31° - +38° on anhydrous and solvent-free basis	+35 °
Solubility	Complies	Complies
Sulphated ashes	NMT 0.50%	0,00 %
ASSAY		
Assay HPLC (USP)	98.0% - 102.0% on the anhydrous, solvent free basis	99,50 %
IMPURITIES		
Isopropyl diphenyl pentanoate	NMT 0.10 %	N.Q.
15(S)-latanoprost	NMT 0.30%	N.Q.
5-trans-latanoprost	NMT 0.30%	0,08 %
Every single unknown impurity	NMT 0.10%	0,06 %
Total impurities	NMT 0.50 %	0,13 %
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.
Ethyl acetate	NMT 5000 ppm	1321 ppm

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

Verona, 02/08/2019

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Approved by QA Manager

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 it n. 12437910156

Stabilimenti/factories:

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

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

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

Complies with cUSP

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