

NEWCHEM

CERTIFICATE OF ANALYSIS LATANOPROST

Batch: **NW2938**

Manuf. date: **12/2016**
Retest date: **01/2019**
Expiration date: **12/2019**

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	+35 °
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.Q.
15(S)-latanoprost	NMT 0.30%	N.Q.
5-trans-latanoprost	NMT 0.30%	0,28 %
Every single unknown Impurity	NMT 0.10%	N.Q.
Total impurities	NMT 0.50 %	N.Q.
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

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, 03/01/2017

Page 1 of 2

Approved by QA Manager



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RESIDUAL SOLVENTS		
Ethyl acetate	NMT 5000 ppm	1202 ppm
Tetrahydrofuran	NMT 500 ppm	N.D.
Dimethylformamide	NMT 100 ppm	38 ppm

Complies with cUSP

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

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