

NEWCHEM

CERTIFICATE OF ANALYSIS

LATANOPROST

Batch: **NU1653**

Manuf. date: **07/2014**

Retest date: **08/2016**

Expiration date: **07/2017**

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%	0,07 %
ASSAY		
Assay HPLC [USP]	98,0% - 102,0% on the anhydrous, solvent free basis	98,3 %
RESIDUAL SOLVENTS		
Ethanol	NMT 5000 ppm	N.D.
Isopropyl alcohol	NMT 2500 ppm	N.D.
Tert-butyl-methyl-ether	NMT 500 ppm	N.D.
n-Hexane	NMT 150 ppm	N.D.
Isopropyl ether	NMT 5000 ppm	N.D.
Ethyl acetate	NMT 5000 ppm	683 ppm
Tetrahydrofuran	NMT 500 ppm	N.D.
Dimethylformamide	NMT 100 ppm	N.D.
IMPURITIES		
Isopropylidiphenylpentanoate	NMT 0.10 %	N.D.
15(S)-latanoprost	NMT 0.30%	0,11 %
5-trans-latanoprost	NMT 0.30%	N.D.
Every single unknown impurity	NMT 0.10%	0,06 %
Total impurities	NMT 0.50 %	0,06 %
Related Compound E	NMT 0.10 %	0,00 %

Complies with cUSP

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

Verona, 07/08/2014

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Approved by QA/QC Director

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