

Certificate of Analysis

Productname: Latanoprostum (Latanoprost)
Number of analysis/Inspection Code: 1 / KEUR-197777B
Batchnumber: 22J04-F12-384710
Reference code / No.: 4095 / NC1901
Analysed according to: USPNF 22/2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Colourless to slightly yellow oil	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Assay
Residue on ignition	<=0,50	0,10		
Organic impurities	Conform	Conform		HPLC
Isopr.diph.phph.pentanoate	<=0,1	<0,05	%	
Latanoprost rel subst. B	<=0,5	<0,05	%	
Latanoprost rel subst. A	<=3,5	0,1	%	
Any other impurity	<=0,1	0,1	%	
Total impurities	<=0,5	0,1	%	
Latanoprost rel subst. E	<=0,2	0,0	%	HPLC
Specific optical rotation	+31 - +38	+35	°	
Water (Karl Fischer)	<=2,0	0,5	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Latanoprost	94,0 - 102,0	99,1	%	Anhydrous and solvent-free
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Newchem Spa - SMS (Pavia) / IT
CEP :

Release:
Anthony Amoureux
Qualified Person

06/29/23

Expiration: 30-07-25

Conclusion: APPROVED

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