

Certificate of Analysis

Productname: **Latanoprostum (Latanoprost)**
Number of analysis/Inspection Code: 1 / KEUR-198736B
Batchnumber: **23F08-F01-385504**
Reference code / No.: 4095 / ND1234
Analysed according to: **USPNF 23/1**

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	0,00		
Organic impurities	Conform	Conform		HPLC
Orlistat rel.subst.C	<=0,15	Not detected	%	
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	<0,05	%	
Total impurities	<=0,5	0,1	%	
Latanoprost rel subst. E	<=0,2	0,0	%	HPLC
Specific optical rotation	+31 - +38	+34	°	
Water (Karl Fischer)	<=2,0	0,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Latanoprost	94,0 - 102,0	99,2	%	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

14-03-24

Expiration: 30-04-26

Conclusion: APPROVED

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