

Certificate of Analysis

Productname: Latanoprostum (Latanoprost)
Number of analysis/Inspection Code: 1 / KEUR-193937B
Batchnumber: 22A19-F02-381300
Reference code / No.: 4095 / NB1357
Analysed according to: USP 43

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		0,00		
Organic impurities	Conform	Conform		HPLC
Isopr.diph.phph.pentanoate	<=0,1	Not detected	%	
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	+35	°	
Water (Karl Fischer)	<=2,0	0,3	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Latanoprost	94,0 - 102,0	99,5	%	Anhydrous and solvent-free
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Anthony Amoureux
 Qualified Person

03/11/22

Expiration: 05-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.