Certificate of Analysis

Product name: Latanoprostum
Batch number / Weight: 24J30-B18-010991 / 5 mg
Producer / Producer Batch Number: Newchem SpA (Pavia) / NE1904
Analyzed according to: USP
Number of Analysis / Certificate no.: 24J30-B18 / QO0016618

	Requirement	Result	Unit	Standard remark
Appearance	Colourless to slightly yellow oil	Conform		
Identification	A,B	Conform		
Organic impurities	Acc. to USP	Conform		
Latanoprost rel subst. C	<=0,15	0,000	%	
Isopr.diph.phorylpentanoate	<=0,1	<0,05	%	
Latanoprost rel subst. B	<=0,5	0,05	%	
Latanoprost rel subst. A	<=3,5	0,17	%	
Any impurity	<=0,1	0,07	%	
Total impurities (excluding rel subst, A, B)	<=0,5	0,07	%	
Latanoprost rel subst. E	<=0,2	0,00	%	
Specific optical rotation	(+31) - (+38)	+36,1	°	
Water (Karl Fischer)	<=2,0	0,20	%	
Residue on ignition	<=0,50	0,22	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	94,0 - 102,0	101,62	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE LAB

Release:

5-6-2025
Ewelina Gadzinowska
Qualified Person

Expiration: 30-6-2027
Conclusion: APPROVED

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