



TECHNICAL DATA SHEET

151384-TDS-ENG-2023

LATANOPROST EP		
DESCRIPTION DCI: LATANOPROST		DESCRIPTION DOE: LATANOPROST
CAS N°: 130209-82-4	EC N°: 634-172-9	AEMPS CODE: 2788A
MOL. WEIGHT: 432.59	MOL. FORMULA: C ₂₆ H ₄₀ O ₅	ARTICLE CODE: 151384

ATTRIBUTES	SHOULD BE
Appearance	Clear, colourless or yellow, viscous, oily liquid
Solubility	Practically insoluble in water, very soluble in acetonitrile, freely soluble in anhydrous ethanol
Identification A	Complies
Identification B	Complies
Specific optical rotation	+32.0 / +37.0
Related substances	
Impurity F	=< 3.5 %
Impurity E	=< 0.4 %
Unspecified impurities	=< 0.10 %
Sum of impurities other than F	=< 1.0 %
Impurity H	=< 0.15 %
Water	=< 0.5 %
Assay	94.0 - 102.0 %
Residual solvents	
Acetone	=< 1000 ppm
Isopropyl alcohol	=< 1000 ppm
Methylene Chloride	=< 600 ppm
n-Heptane	=< 1000 ppm
Ethyl acetate	=< 1000 ppm
Tetrahydrofuran	=< 200 ppm
Toluene	=< 250 ppm
tert-butylmethyleter	=< 300 ppm
Dimethylformamide	=< 880 ppm
Microbiological control	
TAMC	=< 2000 CFU/g
TYMC	=< 200 CFU/g

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the container in tightlyclosed at 2 - 8 °C. Protect from light and heat.

REMARKS

Latanoprost is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in



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accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties

Reduces intraocular pressure

According to published studies, it has been observed that the administration of LATANOPROST eye drops for the treatment of glaucoma can stimulate the growth of eyelashes.

Other studies talk about the possible use of LATANOPROST in hair growth.

Applications

Treatment of patients with open-angle glaucoma or ocular hypertension.

Published studies speak of the use of LATANOPROST in alopecia areata and androgenetic alopecia with results after 8 weeks of treatment.

Posology

Glaucoma

A drop of an ophthalmic solution is instilled at 0.005% once a day, preferably at night.

Toxicity and side effects

LATANOPROST eye drops can produce a gradual increase in brown pigmentation in the iris with prolonged use, because it increases the melanin content of the melanocytes. Rarely it has been described that the eyelashes become darker, denser and longer, and the eyelid skin darkens.

Precautions

Safety and efficacy in children / adolescents under 18 years of age have not been established. Therefore, the administration of LATANOPROST in children / adolescents under 18 years of age is not recommended.

It should not be administered during pregnancy and lactation.