



TECHNICAL DATA SHEET

009410-TDS-ENG-2021

LATANOPROST USP		
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: 009410

ATTRIBUTES	SHOULD BE
Appearance	Colourless or pale yellow oil
Identification A	Complies
Identification B	Complies
Assay	94.0 - 102.0 %
Residue on ignition	=< 0.50 %
Organic impurities	
Isopropyl diphenylphosphoryl pentanoate	=< 0.1 %
Latanoprost Related Compound B	=< 0.5 %
Latanoprost Related Compound A	=< 3.5 %
Unspecified impurities	=< 0.1 %
Total impurities	=< 0.5 %
Limit Latanoprost related compound E	=< 0.2 %
Optical rotation	+31° / +38°
Water	=< 2.0 %
Residual solvents	
Ethyl acetate	=< 5000 ppm
Isopropyl ether	=< 5000 ppm
Isopropyl alcohol	=< 2500 ppm
Methylene Chloride	=< 600 ppm
tert-butylmethyleter	=< 500 ppm
Tetrahydrofuran	=< 500 ppm
n-Hexane	=< 150 ppm
Dimethylformamide	=< 100 ppm

COMPLIES WITH

USP 2021

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 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,



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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.