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Latanoprost Eye Drops

General Notices

Details for the public consultation of this monograph are as follows:

EAG/Panel/Working Party	Medicinal Chemicals 2
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Deadline for Comment	30th September 2026
Target Publication Date (subject to change)	BP 2028
Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Acidity or alkalinity** Specific test concentration removed. **Related substances** Limits revised to limi impurities E and F as a sum.

Action and use

Prostaglandin ($PGF_{2\alpha}$) analogue; treatment of raised intraocular pressure.

DEFINITION

Latanoprost Eye Drops are a sterile solution of Latanoprost in a suitable vehicle.

The eye drops comply with the requirements stated under Eye Preparations and with the following requirements.

Content of latanoprost, $C_{26}H_{40}O_5$

93.5 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 190 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2);
the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Acidity or alkalinity

pH 5.8 to 7.5, Appendix V L.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in mobile phase A.

(1) Dilute a volume of the eye drops, if necessary, to produce a solution containing 0.005% w/v of Latanoprost.
(2) Dilute 1 volume of solution (1) to 50 volumes.
(3) 0.00005% w/v of *latanoprost for system suitability EPCRS*.
(4) 0.00015% w/v of *latanoprost impurity H EPCRS*.
(5) Dilute 1 volume of solution (2) to 20 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *base-deactivated end-capped octadecylsilyl silica gel for chromatography* (3 µm) (ACE C18 is suitable).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use a column temperature of 35°.
(e) Use an autosampler temperature of 4°.
(f) Use a detection wavelength of 208 nm.
(g) Inject 100 µL of each solution.

MOBILE PHASE

Mobile phase A 40 volumes of *acetonitrile R1* and 60 volumes of a 0.34% w/v solution of *potassium dihydrogen orthophosphate* previously adjusted to pH 3.0 with *orthophosphoric acid*.

Mobile phase B *Acetonitrile R1*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-50	100	0	isocratic
50-60	100→75	0→25	linear gradient

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
60-70	75	25	isocratic
70-71	75→100	25→0	linear gradient
71-82	100	0	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *peak-to-valley ratio* is at least 3.0, where *Hp* is the height above the baseline of the peak due to impurity E+F and *Hv* is the height above the baseline of the lowest point of the curve separating this peak from the peak due to latanoprost.

CALCULATION OF IMPURITIES

For each impurity, use the concentration of latanoprost in solution (2).

For the reporting threshold, use the concentration of latanoprost in solution (5).

For peak identification, use solutions (3) and (4).

Latanoprost retention time: about 29 minutes.

Relative retention: impurity H, about 0.2; impurity E+F; about 1.05.

LIMITS

— sum of impurities E and F: not more than 3.9%;

— impurity H: not more than 3.0%;

— unspecified impurities: for each impurity, not more than 1.0%;

— total impurities, excluding impurity E+F: not more than 3.0%;

— reporting threshold: 0.1%.

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions prepared in mobile phase A described under Related Substances.

(1) Dilute a volume of the eye drops, if necessary, to produce a solution containing 0.001% w/v of Latanoprost.
(2) 0.001% w/v of *latanoprost EPCRS*.
(3) 0.001% w/v of *latanoprost for system suitability EPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *peak-to-valley ratio* is at least 2.0, where *Hp* is the height above the baseline of the peak due to impurity E+F and *Hv* is the height above the baseline of the lowest point of the curve separating this peak from the peak due to latanoprost.

DETERMINATION OF CONTENT

Calculate the content of $C_{26}H_{40}O_5$ in the eye drops from the chromatograms obtained and using the declared content of $C_{26}H_{40}O_5$ in *latanoprost EPCRS*.

STORAGE

Latanoprost Eye Drops should be stored at a temperature of 2° to 8°.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities E, F and H listed under Latanoprost.