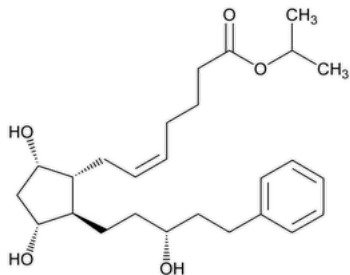


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Latanoprost

Change to read:



$C_{26}H_{40}O_5$ ▲432.60▲ (USP 1-Dec-2022)

5-Heptenoic acid, 7-[3,5-dihydroxy-2-(3-hydroxy-5-phenylpentyl)cyclopentyl]-1-methylethyl ester, [1R-[1α(Z),2β(R*),3α,5α]]-;

Isopropyl (Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate CAS RN®: 130209-82-4; UNII: 6Z5B6HVF60.

DEFINITION

Latanoprost contains NLT 94.0% and NMT 102.0% of latanoprost ($C_{26}H_{40}O_5$), calculated on the anhydrous and solvent-free basis.

[CAUTION—Wear protective glasses and gloves while handling the material. Avoid contact during pregnancy or while nursing.]

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197F ▲or 197A▲ (USP 1-Dec-2022)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Mobile phase: [Chromatographic hexane](#) and [dehydrated alcohol](#) (94:6)

System suitability solution: 2.0 mg/mL of [USP Latanoprost RS](#) and 20 µg/mL of [USP Latanoprost Related Compound A RS](#) prepared as follows. Transfer [USP Latanoprost RS](#) and [USP Latanoprost Related Compound A RS](#) into a suitable volumetric flask, dissolve in [dehydrated alcohol](#) equivalent to 20% of the final volume, and dilute with [chromatographic hexane](#) to volume.

Standard solution: ▲2.0 mg/mL of [USP Latanoprost RS](#) prepared as follows. Transfer [USP Latanoprost RS](#) into a suitable volumetric flask, dissolve in [dehydrated alcohol](#) equivalent to 20% of the final volume, and dilute with [chromatographic hexane](#) to volume.▲ (ERR 1-Dec-2022)

Sample solution: ▲2.0 mg/mL of Latanoprost prepared as follows. Transfer Latanoprost into a suitable volumetric flask, dissolve in [dehydrated alcohol](#) equivalent to 20% of the final volume, and dilute with [chromatographic hexane](#) to volume.▲ (ERR 1-Dec-2022)

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.0-mm × 25-cm; 5-µm packing [L3](#)

Temperatures

▲Autosampler: 5°▲ (USP 1-Dec-2022)

Column: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for latanoprost and latanoprost related compound A are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 2.0 between latanoprost and latanoprost related compound A, *System suitability solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of latanoprost ($C_{26}H_{40}O_5$) in the portion of Latanoprost taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area ▲ of latanoprost ▲ (USP 1-Dec-2022) from the *Sample solution*

r_S = peak area ▲ of latanoprost ▲ (USP 1-Dec-2022) from the *Standard solution*

C_S = concentration of [USP Latanoprost RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Latanoprost in the *Sample solution* (mg/mL)

Acceptance criteria: 94.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.50%

Change to read:

- **ORGANIC IMPURITIES**

Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

▲ **Standard stock solution:** 0.3 mg/mL of [USP Orlistat Related Compound C RS](#) in a mixture of [chromatographic hexane](#) and [dehydrated alcohol](#) (80:20) prepared as follows. Transfer [USP Orlistat Related Compound C RS](#) into a suitable volumetric flask, dissolve in [dehydrated alcohol](#) equivalent to 20% of the final volume, and dilute with [chromatographic hexane](#) to volume. ▲ (USP 1-Dec-2022)

Standard solution: 0.04 mg/mL of [USP Latanoprost RS](#) ▲ and 0.003 mg/mL of [USP Orlistat Related Compound C RS](#) ▲ (USP 1-Dec-2022) in a mixture of [chromatographic hexane](#) and [dehydrated alcohol](#) (80:20) prepared as follows. Transfer [USP Latanoprost RS](#) into a suitable volumetric flask, dissolve in [dehydrated alcohol](#) equivalent to 20% of the final volume, ▲ add a suitable amount of the *Standard stock solution*, ▲ (USP 1-Dec-2022) and dilute with [chromatographic hexane](#) to volume.

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between latanoprost and latanoprost related compound A, *System suitability solution*

Relative standard deviation: NMT 5.0% ▲ for latanoprost and orlistat related compound C, ▲ (USP 1-Dec-2022) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

▲ Calculate the percentage of orlistat related compound C in the portion of Latanoprost taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of orlistat related compound C from the *Sample solution*

r_S = peak area of orlistat related compound C from the *Standard solution*

C_S = concentration of [USP Orlistat Related Compound C RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Latanoprost in the *Sample solution* (mg/mL) ▲ (USP 1-Dec-2022)

Calculate the percentage of ▲ any other ▲ (USP 1-Dec-2022) impurity in the portion of Latanoprost taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak area of ▲ any other ▲ (USP 1-Dec-2022) impurity from the *Sample solution*

r_S = peak area of latanoprost from the *Standard solution*

C_S = concentration of [USP Latanoprost RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Latanoprost in the *Sample solution* (mg/mL)

F = relative response factor for each individual impurity (see [Table 1](#))