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Travoprost Ophthalmic Solution

DEFINITION

Travoprost Ophthalmic Solution is a sterile buffered aqueous solution of Travoprost. It contains NLT 90.0% and NMT 110.0% of the labeled amount of travoprost ($C_{26}H_{35}F_3O_6$). It may contain suitable stabilizers, buffers, and antimicrobial agents.

[CAUTION—Great care should be taken when handling the active ingredient to avoid contact with the body.]

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum 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

Buffer: 2.18 mg/mL of [sodium 1-octanesulfonate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.5.

Mobile phase: [Acetonitrile](#) and *Buffer* (17:33)

Standard solution: 0.04 mg/mL of travoprost from [USP Travoprost RS](#) in a mixture of [acetonitrile](#) and [water](#) (3:7)

Sample solution: Use Ophthalmic Solution without dilution.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. For *Identification B*, use a diode array detector in the range of 190–400 nm.

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Flow rate: 2.0 mL/min

Injection volume: 100 μL

System suitability

Sample: *Standard solution*

[NOTE—[USP Travoprost RS](#) contains a small percentage of the 5,6-*trans* isomer. The relative retention times for travoprost and the 5,6-*trans* isomer are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between travoprost and the 5,6-*trans* isomer

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of travoprost ($C_{26}H_{35}F_3O_6$) in the portion of Ophthalmic Solution taken:

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

r_U = peak response of travoprost from the *Sample solution*

r_S = peak response of travoprost from the *Standard solution*

C_S = concentration of [USP Travoprost RS](#) (IRA 1-Sep-2020) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES**• LIMIT OF TRAVOPROST RELATED COMPOUND A**

Buffer: Add 1.0 mL of [phosphoric acid](#) to 1.0 L of [water](#), and adjust with [sodium hydroxide](#) to a pH of 3.0.

Mobile phase: [Acetonitrile](#) and *Buffer* (6:19)

Standard solution: 0.3 µg/mL of [USP Travoprost Related Compound A RS](#) in a mixture of [acetonitrile](#) and [water](#) (1:4)

Sample solution: Use Ophthalmic Solution without dilution.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 5-cm; 3-µm packing [L1](#)

Flow rate: 3.0 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 10.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of travoprost related compound A in the portion of Ophthalmic Solution taken:

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

r_U = peak response of travoprost related compound A from the *Sample solution*

r_S = peak response of travoprost related compound A from the *Standard solution*

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

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

Acceptance criteria: NMT 1.0%

Change to read:**• LIMIT OF DEGRADATION PRODUCTS**

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Ophthalmic Solution taken:

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

r_U = peak response of each degradation product from the *Sample solution*

r_S = peak response of travoprost from the *Standard solution*

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

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

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#).

Table 1