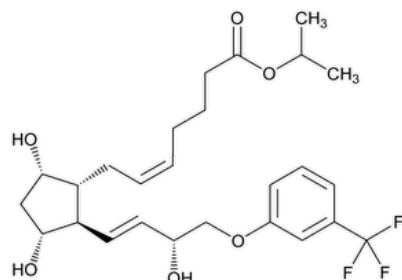


Status: Currently Official on 17-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocId: GUID-D1797DD9-B8F5-4E00-8A36-136E2E5785D2_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M803_01_01
 DOI Ref: xpi9u

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Travoprost



$C_{26}H_{35}F_3O_6$ 500.55

[1R-[1 α (Z),2 β (1E,3R*),3 α ,5 α]]-7-[3,5-Dihydroxy-2-[3-hydroxy-4-[3-(trifluoromethyl)phenoxy]-1-butenyl] cyclopentyl]-5-heptenoic acid, 1-methylethyl ester;

Isopropyl (Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(1E,3R)-3-hydroxy-4-[(α,α,α -trifluoro-*m*-tolyl)oxy]-1-butenyl] cyclopentyl]-5-heptenoate CAS RN®: 157283-68-6; UNII: WJ68R08KX9.

DEFINITION

Travoprost contains NLT 96.0% and NMT 102.0% of travoprost ($C_{26}H_{35}F_3O_6$), calculated on the anhydrous and solvent-free basis.

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

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Standard solution: Use [USP Travoprost RS](#).

Sample solution: Prepare as directed in the Assay.

Chromatographic system

Adsorbent: Chromatographic plate coated with silica gel that contains 20% silver nitrate

Application volume: 5 μ L. [NOTE—To keep the spot size small, it is usually necessary to apply approximately 1–2 μ L at a time, allowing the spot to dry between each application.]

Developing solvent system: Ethyl acetate and ethanol (4:1)

Spray reagent: 20% phosphomolybdic acid in ethanol

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Spray the plate with *Spray reagent*, and heat it in an oven at 80°–100°. The travoprost will appear as black spots.

Acceptance criteria: Meets the requirements

• 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

• PROCEDURE

Buffer: Add 2.0 mL of phosphoric acid to 1 L of water. Adjust with sodium hydroxide to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (3:7)

Standard solution: Use [USP Travoprost RS](#) without dilution (0.5 mg/mL).

Sample solution: Transfer 25 mg of Travoprost to a 50-mL volumetric flask, and dissolve in 15 mL of acetonitrile. Add 25 mL of water, mix, and wait until the solution reaches room temperature. Dilute with water to volume, and mix.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm
Column: 4.6-mm × 5-cm; packing L1
Flow rate: 3.0 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 about 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between travoprost and the 5,6-*trans* isomer
Column efficiency: NLT 1500 theoretical plates
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of travoprost (C₂₆H₃₅F₃O₆) in the portion of Travoprost taken:

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

r_U = peak area from the *Sample solution*
 r_S = peak area from the *Standard solution*
 C_S = concentration of [USP Travoprost RS](#) in the *Standard solution* (mg/mL)
 C_U = concentration of Travoprost in the *Sample solution* (mg/mL)

Acceptance criteria: 96.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• **ORGANIC IMPURITIES**

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

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Travoprost taken:

$$\text{Result} = (r_U/r_T) \times (1/F) \times 100$$

r_U = peak response for each individual impurity
 r_T = sum of the responses of all the peaks
 F = relative response factor (see [Table 1](#))

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

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Travoprost related compound A	0.11	1.0	0.2
Epoxide derivative ^a	0.55	1.0	0.4
15- <i>epi</i> Diastereomer ^b	0.90	1.1	0.1