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Add the following:

▲Latanoprost Compounded Topical Solution

DEFINITION

Latanoprost Compounded Topical Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of latanoprost ($C_{26}H_{40}O_5$).

Prepare Latanoprost Compounded Topical Solution 0.1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*). For this preparation, a separate stock solution of latanoprost 10 mg/g needs to be prepared.

Latanoprost	100 mg
Propylene Glycol, a sufficient quantity to make	10 g

Prepare a latanoprost stock solution by weighing *Latanoprost* in a suitable container. Add a sufficient amount of *Propylene Glycol* to bring to final weight. Seal the container and mix by using ultrasonication for 15 min.

Latanoprost 10 mg/g stock solution	1 g (equivalent to 10 mg of latanoprost)
Alcohol	20 mL
Pracamac Oil[a]	5 mL
Purified Water, a sufficient quantity to make	100 mL

[a] PCCA, Houston, TX.

Add *Latanoprost 10 mg/g stock solution*, *Alcohol*, and *Pracamac Oil* to an appropriately sized container. Add approximately 80 mL of *Purified Water* and mix well. Add a sufficient amount of *Purified Water* to bring to final volume and mix well.

ASSAY

• **Procedure**

Solution A: 0.1% (v/v) trifluoroacetic acid in water

Solution B: 0.1% (v/v) trifluoroacetic acid in acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
1.5	0	100
1.6	70	30
2.5	70	30

Standard solution: 0.04 mg/mL of USP Latanoprost RS in methanol

Sample solution: Transfer 2 mL of the Topical Solution into a 5-mL volumetric flask and dilute with methanol to bring to volume. Mix well.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 2.1-mm × 5-cm; 1.7-µm packing L1

Temperatures

Autosampler: 8°

Column: 65°

Flow rate: 1 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

[NOTE—The typical retention time for latanoprost is about 0.99 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of latanoprost ($C_{26}H_{40}O_5$) in the portion of Topical Solution taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 7.0–8.0

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature. NMT 180 days after the date on which it was compounded when stored in a refrigerator.

• **LABELING:** Label it to indicate that it is for external use only and not for use in the eye. Label it to state the *Beyond-Use Date*.

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Latanoprost RS▲ (USP 1-Dec-2021)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LATANOPROST COMPOUNDED TOPICAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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