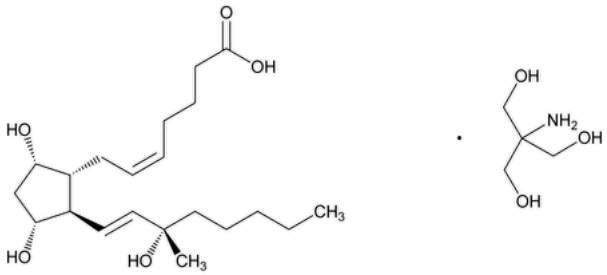
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2021
Document Type: USP Monographs
DocId: GUID-3B7A65C9-A55B-46D3-9279-406D8D1FFB27_3_en-US
DOI: https://doi.org/10.31003/USPNF_M13140_03_01
DOI Ref: q82pr

Carboprost Tromethamine

Change to read:



$C_{21}H_{36}O_5 \cdot C_4H_{11}NO_3$ ▲489.65▲ (ERR 1-May-2021)

Prosta-5,13-dien-1-oic acid, 9,11,15-trihydroxy-15-methyl-, (5*Z*, 9α,11α,13*E*,15*S*)-, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1);

(*Z*)-7-[(1*R*,2*R*,3*R*,5*S*)-3,5-Dihydroxy-2-[(*E*)-(3*S*)-3-hydroxy-3-▲methyloct-1-enyl▲ (ERR 1-May-2021)]cyclopentyl]-5-heptenoic acid compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1);

(15*S*)-15-Methylprostaglandin $F_{2\alpha}$ tromethamine CAS RN®: 58551-69-2; UNII: U4526F86FJ.

DEFINITION

Carboprost Tromethamine contains NLT 95.0% and NMT 105.0% of carboprost tromethamine ($C_{21}H_{36}O_5 \cdot C_4H_{11}NO_3$), calculated on the dried basis.

[Caution—Great care should be taken to prevent inhaling particles of Carboprost Tromethamine and exposing the skin to it.]

IDENTIFICATION

- **A.** **Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**
- **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: 0.02 M monobasic potassium phosphate

Mobile phase: Acetonitrile, methanol, and *Buffer* (20:30:50). Adjust with phosphoric acid to an apparent pH of 3.0.

Diluent: Acetonitrile, methanol, and water (20:30:50)

Standard solution: 1.0 mg/mL of USP Carboprost Tromethamine RS in *Diluent*

Sample solution: 1.0 mg/mL of Carboprost Tromethamine in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 4-mm × 15-cm; 3-µm packing L1

Column temperature: 30 ± 2°

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—See *Table 1* for the relative retention times of *trans*-carboprost and carboprost.]

Suitability requirements

Resolution: NLT 1.2 between *trans*-carboprost and carboprost

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carboprost tromethamine ($C_{21}H_{36}O_5 \cdot C_4H_{11}NO_3$) in the portion of Carboprost Tromethamine taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0% on the dried basis

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.5%
- **Organic Impurities**

Buffer, Mobile phase, and **Diluent:** Prepare as directed in the *Assay*.

Standard stock solution: 1.0 mg/mL of USP Carboprost Tromethamine RS in *Diluent*

System suitability solution: 0.1 mg/mL of 15-epicarboprost in the *Standard stock solution*

Standard solution: 0.025 mg/mL of USP Carboprost Tromethamine RS in *Diluent* from the *Standard stock solution*

Sensitivity solution: 0.001 mg/mL of USP Carboprost Tromethamine RS in *Diluent* from the *Standard stock solution*

Sample solution: 1 mg/mL of Carboprost Tromethamine in *Diluent*

Chromatographic system: Proceed as directed in the *Assay*, except use an *Injection volume* of 20 µL.

System suitability

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

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 1.0 between 15-epicarboprost and *trans*-carboprost; NLT 1.2 between *trans*-carboprost and carboprost, *System suitability solution*

Relative standard deviation: NMT 5.0% for carboprost, *Standard solution*

Signal-to-noise ratio: NLT 10 for carboprost, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Carboprost Tromethamine taken:

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

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of carboprost tromethamine from the *Standard solution*

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

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

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
15-Epicarboprost[a]	0.90	2.0
trans-Carboprost[b]	0.94	3.0
Carboprost	1.0	—
Any individual unspecified impurity	—	0.10
Total impurities	—	4.0

[a] (*Z*)-7-[(1*R*,2*R*,3*R*,5*S*)-3,5-Dihydroxy-2-[(*E*)-(3*R*)-3-hydroxy-3-methyloct-1-enyl]cyclopentyl]-5-heptenoic acid.

[b] (*E*)-7-[(1*R*,2*R*,3*R*,5*S*)-3,5-Dihydroxy-2-[(*E*)-(3*S*)-3-hydroxy-3-methyloct-1-enyl]cyclopentyl]-5-heptenoic acid.

SPECIFIC TESTS

- **Optical Rotation,** *Specific Rotation* ⟨781S⟩

  Sample solution: 10 mg/mL of Carboprost Tromethamine in alcohol

  Acceptance criteria: +18° to +24°

- **Loss on Drying** ⟨731⟩

  Analysis: Dry under vacuum at a pressure not exceeding 5 mm of mercury at 50° for 16 h.

  Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store in a freezer.
- **USP Reference Standards** ⟨11⟩

  USP Carboprost Tromethamine RS

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

Topic/Question	Contact	Expert Committee
CARBOPROST TROMETHAMINE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(4)

Current DocID: GUID-3B7A65C9-A55B-46D3-9279-406D8D1FFB27_3_en-US

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