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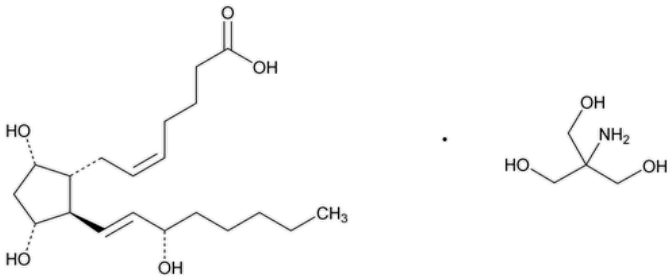
Dinoprost Tromethamine



$C_{20}H_{34}O_5 \cdot C_4H_{11}NO_3$ 475.62

Prosta-5,13-dien-1-oic acid, 9,11,15-trihydroxy-, (5*Z*,9α,11α,13*E*,15*S*)-, compd. with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1).
(*E*,*Z*)-(1*R*,2*R*,3*R*,5*S*)-7-[3,5-Dihydroxy-2-[(3*S*)-(3-hydroxy-1-octenyl)]cyclopentyl]-5-heptenoic acid compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1).

Prostaglandin F_{2a} tromethamine CAS RN®: 38562-01-5; UNII: CT6BBQ5A68.

» Dinoprost Tromethamine contains not less than 95.0 percent and not more than 105.0 percent of $C_{20}H_{34}O_5 \cdot C_4H_{11}NO_3$, calculated on the dried basis. [**Caution—**Great care should be taken to prevent inhaling particles of Dinoprost Tromethamine and exposing the skin to it.]

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Dinoprost Tromethamine RS

Change to read:

Identification, ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197M*.▲ (CN 1-May-2020)

Specific rotation ⟨781S⟩: between +19° and +26°.
Test solution: 20 mg per mL, in alcohol.

Loss on drying ⟨731⟩—Dry it in vacuum at room temperature and at a pressure not exceeding 5 mm of mercury for 16 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩: not more than 0.5%.

Chromatographic purity—[Note—Prepare solutions immediately prior to use.]
Mobile phase—Proceed as directed in the *Assay.*
Standard stock solution—Prepare as directed for *Standard preparation* in the *Assay.*
Standard solution—Transfer 1.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.
Test solution—Prepare as directed for the *Assay preparation.*
Chromatographic system—Proceed as directed in the *Assay.* Chromatograph the *Test solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between dinoprost tromethamine and any other adjacent peak is not less than 1.0.
Procedure—Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of each impurity in the portion of Dinoprost Tromethamine taken by the formula:

$$2.5(C/W)F(r_i/r_S)$$

in which *C* is the concentration, in µg per mL, of USP Dinoprost Tromethamine RS in the *Standard solution; W* is the weight, in mg, of Dinoprost Tromethamine taken to prepare the *Test solution; F* is the relative response factor and is equal to 0.25 for any peak at a relative retention time of about 0.30, 1.7 for any peak at a relative retention time of about 1.15, and 1.0 for any other peak; r_i is the peak response of each impurity obtained from the *Test solution;* and r_S is the peak response of dinoprost tromethamine obtained from the *Standard solution:* not more than 2.0% of any impurity having a relative retention time of about 0.94 is found; not more than 1.5% of any impurity having a relative retention time of about 0.84 is found; not more than 0.5% of any other impurity is found; and not more than 2.0% of all other impurities is found.

Assay—[Note—Prepare solutions immediately prior to use.]
Mobile phase—Prepare a filtered and degassed mixture of water, acetonitrile, and phosphoric acid (750:250:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Dinoprost Tromethamine RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 1.0 mg per mL.

Assay preparation—Transfer about 25.0 mg of Dinoprost Tromethamine, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 200-nm detector and a 3.9-mm × 15-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the column efficiency is not less than 6000 theoretical plates, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{20}H_{34}O_5 \cdot C_4H_{11}NO_3$ in the portion of Dinoprost Tromethamine taken by the formula:

$$25C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Dinoprost Tromethamine RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
DINOPROST TROMETHAMINE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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