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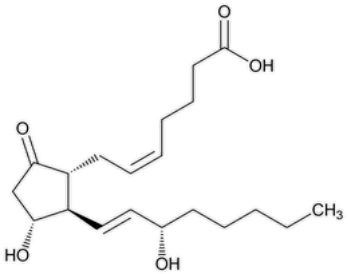
Dinoprostone



$C_{20}H_{32}O_5$ 352.47

Prosta-5,13-dien-1-oic acid, 11,15-dihydroxy-9-oxo-, (5*Z*,11α,13*E*,15*S*)-;
(*E*,*Z*)-(1*R*,2*R*,3*R*)-7-[3-Hydroxy-2-[(3*S*)-(3-hydroxy-1-octenyl)]-5-oxocyclopentyl]-5-heptenoic acid;

Prostaglandin E_2 CAS RN®: 363-24-6; UNII: K7Q1JQR04M.

DEFINITION

Dinoprostone contains NLT 97.0% and NMT 103.0% of dinoprostone ($C_{20}H_{32}O_5$).

[Note—Prepare all solutions in all tests immediately before use.]

IDENTIFICATION

Change to read:

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

• **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**

Solution A: 0.2% (v/v) of 5 N acetic acid in water

Mobile phase: Methanol and *Solution A* (29:21)

System suitability solution: 0.04 mg/mL each of USP Dinoprostone RS and USP Dinoprostone Related Compound C RS in *Mobile phase*

Standard solution: 2.5 mg/mL of USP Dinoprostone RS in *Mobile phase*

Sample solution: 2.5 mg/mL of Dinoprostone in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 3.8 between dinoprostone and dinoprostone related compound C, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dinoprostone ($C_{20}H_{32}O_5$) in the portion of Dinoprostone 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 Dinoprostone RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.0%–103.0%

IMPURITIES

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

Mobile phase, System suitability solution, and **Sample solution:** Prepare as directed in the *Assay*.

Standard stock solution: Prepare as directed for the *Standard solution* in the *Assay*.

Standard solution: Transfer 0.5 mL of the *Standard stock solution* to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 3.8 between dinoprostone and dinoprostone related compound C, *System suitability solution*

Column efficiency: NLT 6000 theoretical plates, *Standard solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

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

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

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
15-Oxo-dinoprostone	0.79	5	—*
15-Epi-dinoprostone	0.85	1.1	—*
8-Isodinoprostone	0.90	1.0	—*
Dinoprostone	1.00	—	—
Dinoprostone related compound C	1.15	1.0	2.0
(5*Z*,13*E*,15*S*)-15-Hydroxy-9-oxoprosta-5, 10,13-	1.80	5	1.0

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
triene-1-oic acid			
(5*Z*,13*E*,15*S*)-15-Hydroxy-9-oxoprosta-5,8(12),13-trien-1-oic acid	1.90	1.43	1.0
Any individual unspecified impurity	—	1.0	0.10

* The sum of these three impurities is NMT 1.0%.

SPECIFIC TESTS

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

Sample solution: 5 mg/mL in alcohol

Acceptance criteria: −82.0° to −90.0°, at 20°

• **Water Determination,** *Method I* ⟨921⟩**:** NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed, light-resistant containers.

• **USP Reference Standards** ⟨11⟩

USP Dinoprostone RS

USP Dinoprostone Related Compound C RS

(*E*)-7-{(1*R*,2*R*,3*R*)-3-Hydroxy-2-[(*S*,*E*)-3-hydroxyoct-1-en-1-yl]-5-oxocyclopentyl}hept-5-enoic acid.

$C_{20}H_{32}O_5$ 352.47

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

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

Chromatographic Database Information: Chromatographic Database

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