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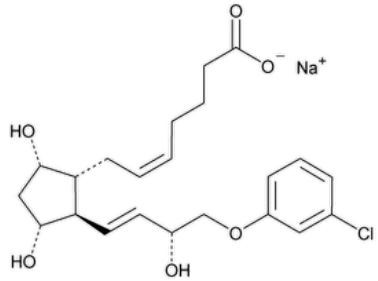
Cloprostenol Sodium



$C_{22}H_{28}ClNaO_6$ 446.90

5-Heptenoic acid, 7-[2-[4-(3-chlorophenoxy)-3-hydroxy-1-butenyl]-3,5-dihydroxycyclopentyl]-, [1α(*Z*),2β(1*E*,3*R**),3α,5α]-, sodium salt, (±)-;

(±)-Sodium (*Z*)-7-[(1*R**,2*R**,3*R**,5*S**)-2-[(*E*)-(3*R**)-4-(*m*-chlorophenoxy)-3-hydroxy-1-butenyl]-3,5-dihydroxycyclopentyl]-5-heptenoate CAS RN®: 55028-72-3; UNII: 886SAV9675.

DEFINITION

Cloprostenol Sodium contains NLT 97.5% and NMT 102.5% of cloprostenol sodium ($C_{22}H_{28}ClNaO_6$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

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

• **B.** **Identification Tests—General, *Sodium* ⟨191⟩**

ASSAY

• **Procedure**

Mobile phase: Chromatographic hexane, dehydrated alcohol, and glacial acetic acid (900:100:1)

Standard solution: 0.8 mg/mL of USP Cloprostenol Sodium RS in dehydrated alcohol

Sample solution: 0.8 mg/mL of Cloprostenol Sodium in dehydrated alcohol

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L3

Flow rate: 1.8 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5 for the cloprostenol peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cloprostenol sodium ($C_{22}H_{28}ClNaO_6$) in the portion of Cloprostenol Sodium 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 Cloprostenol Sodium RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 97.5%–102.5% on the anhydrous basis

IMPURITIES

• **Organic Impurities**

Mobile phase: Chromatographic hexane, dehydrated alcohol, and glacial acetic acid (930:70:1)

Sample solution: 20 mg/mL of Cloprostenol Sodium in dehydrated alcohol

Standard solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*, except use a run time of NLT 2 times the retention time of cloprostenol.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Cloprostenol Sodium taken:

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

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

r_T = sum of the responses all the peaks from the *Sample solution*

Acceptance criteria: Disregard any peak below 0.05%.

Individual impurities: NMT 1.0%

Total impurities: NMT 2.5%

SPECIFIC TESTS

• **Water Determination,** *Method I* ⟨921⟩

Sample solution: 50 mg dissolved in 1 mL of dehydrated alcohol

Acceptance criteria: NMT 3.0%

ADDITIONAL REQUIREMENTS

• **Labeling:** Label it to indicate that it is for veterinary use only.

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

• **USP Reference Standards** ⟨11⟩

USP Cloprostenol Sodium RS

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

Topic/Question	Contact	Expert Committee
CLOPROSTENOL SODIUM	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(1)

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