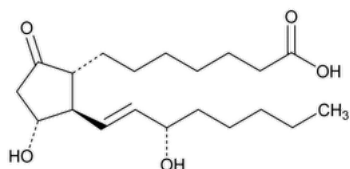


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Alprostadil



$C_{20}H_{34}O_5$ 354.48

Prost-13-en-1-oic acid, 11,15-dihydroxy-9-oxo-, (11 α ,13E,15S)-;

(1R,2R,3R)-3-Hydroxy-2-[(E)-(3S)-3-hydroxy-1-octenyl]-5-oxocyclopentaneheptanoic acid CAS RN®: 745-65-3; UNII: F5TD010360.

DEFINITION

Alprostadil contains NLT 95.0% and NMT 105.0% of alprostadil ($C_{20}H_{34}O_5$), calculated on the anhydrous basis.

[CAUTION—Great care should be taken to prevent inhaling particles of Alprostadil and exposing the skin to it.]

IDENTIFICATION

Change to read:

- **A.** (USP 1-MAY-2022) [SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197M

ASSAY

PROCEDURE

Use freshly prepared solutions.

Mobile phase: [Methanol](#), [acetonitrile](#), and 0.1 M [monobasic potassium phosphate](#) (2:1:2). Adjust with [phosphoric acid](#) to a pH of 3.0.

Diluent: [Methanol](#) and [water](#) (90:10)

Internal standard solution: 0.05 mg/mL of [ethylparaben](#) in Diluent

Standard stock solution: 0.3 mg/mL of [USP Alprostadil RS](#) in Diluent

Standard solution: 0.2 mg/mL of [USP Alprostadil RS](#) prepared by combining 2.0 mL of Standard stock solution with 1.0 mL of Internal standard solution

System suitability stock solution: 4.5 μ g/mL of [USP Prostaglandin A1 RS](#) in Standard stock solution

System suitability solution: Combine 2.0 mL of System suitability stock solution with 1.0 mL of Internal standard solution.

Sample stock solution: 0.3 mg/mL of Alprostadil in Diluent

Sample solution: 0.2 mg/mL of Alprostadil prepared by combining 2.0 mL of Sample stock solution and 1.0 mL of Internal standard solution

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Photodiode array detector or equivalent capable of detecting UV wavelengths of 200–300 nm

Analytical wavelength: 200 nm

Column: 4.6-mm $\times$ 25-cm; packing [L1](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 20 μ L

System suitability

Sample: System suitability solution

Suitability requirements

Resolution: NLT 7.5 between prostaglandin A_1 and alprostadil, and NLT 2.0 between prostaglandin A_1 and ethylparaben

Relative standard deviation: NMT 2.0%, determined from the peak area ratio of alprostadil to ethylparaben

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of alprostadil ($C_{20}H_{34}O_5$) in the portion of Alprostadil taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of alprostadil to the internal standard from the *Sample solution*

R_S = peak area ratio of alprostadil to the internal standard from the *Standard solution*

C_S = concentration of [USP Alprostadil RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 0.3 g

Acceptance criteria: NMT 0.5%

Delete the following:

▲ • LIMIT OF CHROMIUM

Standard stock solution: 3.04 µg/mL of chromium trichloride in 0.05 M nitric acid

Standard solution: 20 ng/mL of chromium (Cr) in alcohol, prepared as follows. Transfer 2 mL of the *Standard stock solution* to a 100-mL volumetric flask, and dilute with alcohol to volume.

Sample solution: 1.0 mg/mL of Alprostadil in alcohol

Blank: Alcohol

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectroscopy

Lamp: Chromium hollow-cathode

Analytical wavelength: 357.9 nm

Atomization type: Graphite furnace

Temperatures

Drying: 100°

Ashing: 1000°

Atomization: 2700°

Injection volume: 20 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of chromium (Cr) in the portion of Alprostadil taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of chromium in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.002% ▲ (USP 1-May-2022)

Delete the following:

▲ • LIMIT OF RHODIUM

Standard stock solution: 100 µg/mL of rhodium in 1.2 M hydrochloric acid, prepared by diluting rhodium chloride hydrate

Standard solution: 50 ng/mL of rhodium (Rh) in alcohol from *Standard stock solution*

Sample solution: 2.0 mg/mL of Alprostadil in alcohol

Blank: Alcohol

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectroscopy

Lamp: Rhodium hollow-cathode

Analytical wavelength: 343.5 nm

Atomization type: Graphite furnace

Temperatures

Drying: 100°

Ashing: 1000°

Atomization: 2800°

Injection volume: 20 µL