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Alprostadil Injection

DEFINITION

Alprostadil Injection is a sterile solution of Alprostadil in Dehydrated Alcohol. It contains NLT 90.0% and NMT 115.0% of the labeled amount of alprostadil ($C_{20}H_{34}O_5$).

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Sample: Dry an amount of Injection, equivalent to 2 mg of alprostadil, on 500 mg of spectroscopic grade potassium bromide at 40°–50° under vacuum. Prepare a pellet from this mixture.

Standard: A solution of [USP Alprostadil RS](#) dissolved in dehydrated alcohol and processed as described in the *Sample*

Acceptance criteria: Meets the requirements

ASSAY

• PROCEDURE

Solution A: 40 mg/mL of α -bromo-2'-acetonaphthone in acetonitrile, freshly prepared

Solution B: 5 mg/mL of diisopropylethylamine in acetonitrile, freshly prepared

Mobile phase: Methylene chloride, 1,3-butanediol, and water (1000:6:0.5)

Internal standard solution: 50 μ g/mL of ethylparaben in methylene chloride

Standard stock solution: 0.5 mg/mL of [USP Alprostadil RS](#) in dehydrated alcohol

Standard solution: 0.13 mg/mL of [USP Alprostadil RS](#), prepared as follows. Gently evaporate a 0.5-mL portion of the *Standard stock solution* to dryness with a stream of nitrogen. Add 150 μ L of *Solution A*, rinse the inside of the container with this solution, and swirl. Add 150 μ L of *Solution B* to the container, rinse the inside of the container with this solution, and swirl. Cap and sonicate to dissolve. Heat the container at 45° for 45 min, swirling occasionally. Sonicate again after heating is complete. Discard the specimen if the entire sample does not dissolve. Evaporate the solution using a stream of nitrogen, add 2.0 mL of *Internal standard solution*, and sonicate to dissolve. Discard the specimen if the entire sample does not dissolve.

Sample solution: Nominally 0.13 mg/mL of alprostadil, prepared as follows. Pool the contents of several containers of the Injection. Gently evaporate a volume, equivalent to 0.25 mg of alprostadil, to dryness using a stream of nitrogen. Proceed as directed for the *Standard solution*, beginning with "Add 150 μ L of *Solution A*".

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.4-mm \times 25-cm; packing L18

Flow rate: 1.5 mL/min

Injection volume: Equal volumes of *Standard solution* and *Sample solution*

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for ethylparaben and alprostadil are about 0.4 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 9.0 between alprostadil and the internal standard

Relative standard deviation: NMT 2.5%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

R_S = peak response 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 = nominal concentration of alprostadil the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

- **BACTERIAL ENDOTOXINS TEST (85):** It contains NMT 5 USP Endotoxin Units/100 µg of alprostadil.
- **STERILITY TESTS (71):** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **WATER DETERMINATION, Method I (921):** NMT 0.4%
- **OTHER REQUIREMENTS:** It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, single-dose containers, preferably of Type I glass. Store in a refrigerator.
- **USP REFERENCE STANDARDS (11):**
[USP Alprostadil RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ALPROSTADIL INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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