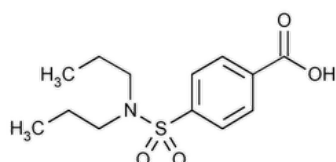


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Probenecid

Change to read:



$C_{13}H_{19}NO_4S$ 285.36

Benzoic acid, 4-[(dipropylamino)sulfonyl]-;
p-(Dipropylsulfamoyl)benzoic acid;

▲4-(Dipropylsulfamoyl)benzoic acid▲ (USP 1-Aug-2022) CAS RN®: 57-66-9; UNII: PO572Z7917.

DEFINITION

Probenecid contains NLT 98.0% and NMT 101.0% of probenecid ($C_{13}H_{19}NO_4S$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K
- **B. SPECTROSCOPIC IDENTIFICATION TESTS (197), Ultraviolet-Visible Spectroscopy:** 197U

Sample solution: 20 µg/mL in [alcohol](#)

Analytical wavelength: 248 nm

Acceptance criteria: Absorptivities, calculated on the dried basis, differ by NMT 3.0%.

ASSAY

Change to read:

PROCEDURE

Solution A: 1% [glacial acetic acid](#) in [water](#)

Solution B: 1% [glacial acetic acid](#) in [acetonitrile](#)

Buffer: 0.05 M [monobasic sodium phosphate](#) in *Solution A*. Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: *Solution B* and *Buffer* (50:50)

Standard solution: 0.50 mg/mL of [USP Probenecid RS](#) in *Mobile phase*

Sample solution: 0.50 mg/mL of Probenecid in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; ▲5-µm▲ (USP 1-Aug-2022) packing L11

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

▲▲ (USP 1-Aug-2022)

Tailing factor: NMT 2.3

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of probenecid ($C_{13}H_{19}NO_4S$) in the portion of Probenecid taken:

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

r_U = peak response ▲ of probenecid ▲ (USP 1-Aug-2022) from the *Sample solution*

r_S = peak response ▲ of probenecid ▲ (USP 1-Aug-2022) from the *Standard solution*

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

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

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Delete the following:

- ▲ [SELENIUM \(291\)](#)

Sample: Mix 100 mg of Probenecid with 100 mg of magnesium oxide

Acceptance criteria: NMT 30 ppm ▲ (USP 1-Aug-2022)

• **ORGANIC IMPURITIES**

Solution A, Solution B, Buffer, Mobile phase, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

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

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

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

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

Acceptance criteria

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

Delete the following:

- ▲ [MELTING RANGE OR TEMPERATURE \(741\)](#): 198°–200° ▲ (USP 1-Aug-2022)

• **ACIDITY**

Sample solution: 20 mg/mL of Probenecid in [water](#) prepared as follows. Transfer 2 g of Probenecid to a suitable container and add 100 mL of [water](#). Heat on a steam bath for 30 min, cool, filter, and dilute with [water](#) to 100 mL.

Titrimetric system

Mode: Direct titration

Titrant: 0.10 N [sodium hydroxide](#)

Endpoint detection: Visual

Analysis: To 25.0 mL of the *Sample solution*, add 1 drop of [phenolphthalein TS](#). Titrate with *Titrant*.

Acceptance criteria: NMT 0.50 mL is required to produce a pink color

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Probenecid RS](#)