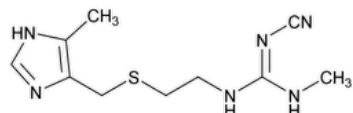


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Cimetidine



$C_{10}H_{16}N_6S$ 252.34

Guanidine, *N*''-cyano-*N*-methyl-*N*'-[2-[(5-methyl-1*H*-imidazol-4-yl)methyl]thio]ethyl]-;

2-Cyano-1-methyl-3-[2-[(5-methylimidazol-4-yl)methyl]thio]ethyl]guanidine CAS RN®: 51481-61-9; UNII: 80061L1WGD.

DEFINITION

Cimetidine contains NLT 98.0% and NMT 102.0% of cimetidine ($C_{10}H_{16}N_6S$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K ▲ or 197A ▲ (USP 1-Aug-2022)

Change to read:

- **B.** ▲ The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*. ▲ (USP 1-Aug-2022)

ASSAY

Change to read:

PROCEDURE

Mobile phase: [Methanol](#), [water](#), and [phosphoric acid](#) (20: 80: 0.03)

Standard stock solution: 0.4 mg/mL of [USP Cimetidine RS](#) prepared as follows. Accurately weigh and transfer an appropriate amount of [USP Cimetidine RS](#) in a suitable flask. Add 20% of the final volume of [methanol](#) to dissolve, and dilute with [water](#) to volume.

Standard solution: 0.01 mg/mL of [USP Cimetidine RS](#) in *Mobile phase* from the *Standard stock solution*

Sample stock solution: 0.4 mg/mL of Cimetidine prepared as follows. Accurately weigh and transfer an appropriate amount of Cimetidine in a suitable flask. Add 20% of the final volume of [methanol](#) to dissolve, and dilute with [water](#) to volume.

Sample solution: 0.01 mg/mL of Cimetidine in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. ▲ For *Identification B*, use a diode array detector in the range of 190–400 nm. ▲ (USP 1-Aug-2022)

Column: 3.9-mm × 30-cm; packing [L1](#)

Flow rate: 2.0 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

▲ **Tailing factor:** NMT 2.0 ▲ (USP 1-Aug-2022)

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cimetidine ($C_{10}H_{16}N_6S$) in the portion of Cimetidine taken:

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

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

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

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

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

Change to read:

• ORGANIC IMPURITIES

Mobile phase: Mix 240 mL of [methanol](#), 0.3 mL of [phosphoric acid](#), 940 mg of [sodium 1-hexanesulfonate](#), and sufficient [water](#) to make 1 L, and filter.

Standard solution: 0.80 µg/mL of [USP Cimetidine RS](#) in *Mobile phase*

Sample solution: 0.4 mg/mL of Cimetidine in *Mobile phase*. [▲]Sonicate for NLT 15 min to dissolve. [▲] (USP 1-Aug-2022)

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing [L1](#)

Flow rate: 2.0 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

[▲]**Tailing factor:** NMT 2.0 [▲] (USP 1-Aug-2022)

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

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

C_U = concentration of Cimetidine in the *Sample solution* (µg/mL)

Acceptance criteria: [▲]See [Table 1](#).

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Cimetidine	1.0	—
Any individual impurity	—	0.2