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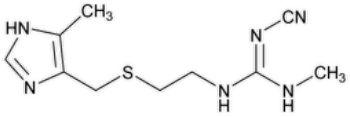
Cimetidine



$C_{10}H_{16}N_6S$ 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

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Total impurities	—	1.0▲ (USP 1-Aug-2022)

SPECIFIC TESTS

Delete the following:

▲• **Melting Range or Temperature** ⟨741⟩**:** 139°–144°▲ (USP 1-Aug-2022)

• **Loss on Drying** ⟨731⟩

Analysis: Dry a sample at 110° for 2 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards** ⟨11⟩

USP Cimetidine RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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