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Cimetidine Injection

DEFINITION

Cimetidine Injection is a sterile solution of Cimetidine Hydrochloride in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of cimetidine ($C_{10}H_{16}N_6S$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: Transfer 200 mL of methanol and 0.3 mL of phosphoric acid to a 1000-mL volumetric flask, dilute with water to volume, and filter.

Standard stock solution: 0.5 mg/mL of USP Cimetidine Hydrochloride RS in a mixture of methanol and water (1:4)

Standard solution: 12.5 µg/mL of USP Cimetidine Hydrochloride RS in *Mobile phase* from *Standard stock solution*

Sample solution: Nominally 10.0 µg/mL of cimetidine, prepared as follows. Transfer an accurately measured volume of Injection, equivalent to about 2 mg of cimetidine, to a 200-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, *k'*: NLT 0.6

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

M_{r1} = molecular weight of cimetidine, 252.34

M_{r2} = molecular weight of cimetidine hydrochloride, 288.81

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.5 USP Endotoxin Unit/mg of cimetidine hydrochloride

• **pH ⟨791⟩:** 3.8–6.0

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

• **USP Reference Standards ⟨11⟩**

USP Cimetidine Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

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