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Cimetidine Tablets

DEFINITION
Cimetidine Tablets contain 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: 0.4 mg/mL of USP Cimetidine RS in methanol and water (1:4), prepared by initially dissolving the USP Cimetidine RS in methanol using 20% of the final volume and diluting that solution 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: Weigh, and finely powder NLT 20 Tablets. Transfer a portion of the powder, equivalent to about 100 mg of cimetidine, to a 250-mL volumetric flask. Add 50 mL of methanol, shake for 2 min, add 40 mL of water, sonicate for 15 min, and dilute with water to volume.

Sample solution: Transfer 5.0 mL of the *Sample stock solution* 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: 2.0 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: Calculate the percentage of the labeled amount of cimetidine ($C_{10}H_{16}N_6S$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**

Medium: 0.01 N hydrochloric acid; 900 mL

Apparatus 1: 100 rpm. A 20-mesh basket may be used for 800-mg strength Tablets.

Time: 15 min

Standard solution: USP Cimetidine RS in *Medium*

Sample solution: Filtered solution under test, diluted with *Medium* to a concentration that is similar to that of the *Standard solution*

Detector: UV, the wavelength of maximum absorbance at about 218 nm

Tolerances: NLT 80% (*Q*) of the labeled amount of cimetidine ($C_{10}H_{16}N_6S$) is dissolved.

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers at controlled room temperature.
- **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 TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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