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Methenamine Hippurate Tablets

DEFINITION

Methenamine Hippurate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of methenamine hippurate ($C_6H_{12}N_4 \cdot C_9H_9NO_3$).

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197M**▲ (CN 1-May-2020)

Sample: A portion of finely powdered Tablets

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Sample solution: Transfer an equivalent to 700 mg of methenamine hippurate from finely powdered Tablets (NLT 20) to a 250-mL conical flask. Add 50 mL of alcohol, then add thymolphthalein TS.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Visual

Analysis: Titrate the *Sample solution* with *Titrant*. Perform a blank determination on a mixture of 50 mL of alcohol and 20 mL of water, and make any necessary correction. Each mL of 0.1 N sodium hydroxide is equivalent to 31.94 mg of methenamine hippurate ($C_6H_{12}N_4 \cdot C_9H_9NO_3$).

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• Dissolution ⟨711⟩

Test 1

Medium: Water; 900 mL

Apparatus 2: 100 rpm

Time: 30 min

Standard solution: 22 µg/mL of USP Methenamine Hippurate RS

Instrumental conditions

Mode: UV

Analytical wavelength: Maxima at about 227 nm

Analysis: Determine the quantity of methenamine hippurate ($C_6H_{12}N_4 \cdot C_9H_9NO_3$) dissolved of filtered portions of the solution under test, suitably diluted with water if necessary, in comparison with the *Standard solution*.

Tolerances: NLT 80% (*Q*) of the labeled amount of methenamine hippurate ($C_6H_{12}N_4 \cdot C_9H_9NO_3$) is dissolved.

Test 2

[Note—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.]

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Standard solution: 22 µg/mL of USP Methenamine Hippurate RS

Instrumental conditions

Mode: UV

Analytical wavelength: Maxima at about 227 nm

Analysis: Determine the quantity of methenamine hippurate ($C_6H_{12}N_4 \cdot C_9H_9NO_3$) dissolved of filtered portions of the solution under test, suitably diluted with water if necessary, in comparison with the *Standard solution*.

Tolerances: NLT 80% (*Q*) of the labeled amount of methenamine hippurate ($C_6H_{12}N_4 \cdot C_9H_9NO_3$) is dissolved.

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

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.
- **USP Reference Standards** ⟨11⟩
  USP Methenamine Hippurate RS

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

Topic/Question	Contact	Expert Committee
METHENAMINE HIPPURATE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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