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Methenamine Mandelate Tablets

DEFINITION

Methenamine Mandelate Tablets contain NLT 95.0% and NMT 105.0% of the labeled amount of methenamine mandelate ($C_6H_{12}N_4 \cdot C_8H_8O_3$).

IDENTIFICATION

Change to read:

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

Sample: Triturate a portion of finely powdered Tablets, equivalent to 5.0 mg of methenamine mandelate, with 5 mL of chloroform, and pass through a 0.45-µm membrane filter. Evaporate the solvent, and allow the residue to air-dry.

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Sample solution: Transfer an equivalent to 60 mg of methenamine mandelate, from NLT 20 finely powdered Tablets, to a 250-mL conical flask. Add 15 mL of dehydrated alcohol, stir to dissolve, and add 40 mL of chloroform.

Titrimetric system

Mode: Direct titration

Titrant: 0.05 N silver nitrate in dehydrated alcohol prepared as follows. Dissolve by stirring 8.5 g of silver nitrate in 1000 mL of dehydrated alcohol. Transfer 100 mg of sodium chloride, previously dried at 110° for 2 h, to a 100-mL beaker, and dissolve in 50 mL of water. Titrate with the silver nitrate solution to the potentiometric endpoint, using a silver billet indicator electrode and a silver–silver chloride double-junction reference electrode containing a potassium nitrate salt bridge. Calculate the normality of the titrant.

Endpoint detection: Potentiometric

Analysis: Titrate the *Sample solution* with *Titrant*, determining the endpoint potentiometrically, using a silver billet indicator electrode and a silver–silver chloride double-junction reference electrode containing a potassium nitrate salt bridge. Each mL of 0.05 N silver nitrate is equivalent to 7.308 mg of methenamine mandelate ($C_6H_{12}N_4 \cdot C_8H_8O_3$).

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

For uncoated or plain coated Tablets

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Standard solution: USP Methenamine Mandelate RS in *Medium*

Instrumental conditions

Mode: UV

Analytical wavelength: UV maximum at about 257 nm

Analysis: Determine the amount of methenamine mandelate ($C_6H_{12}N_4 \cdot C_8H_8O_3$) dissolved in the portion of the solution under test, passed through a filter of 0.45-µm pore size and suitably diluted with *Medium*, if necessary, in comparison with a *Standard solution* having a known concentration of USP Methenamine Mandelate RS in the same *Medium*.

Tolerances: NLT 75% (*Q*) of the labeled amount of methenamine mandelate ($C_6H_{12}N_4 \cdot C_8H_8O_3$) is dissolved.

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

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP Methenamine Mandelate RS

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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