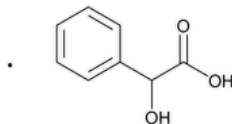
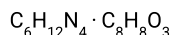
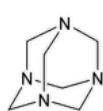


Status: Currently Official on 18-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-ADDC3589-6A29-4382-B238-6B2EE99D5F39_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M50900_04_01
 DOI Ref: 7s6cu

© 2025 USPC
 Do not distribute

Methenamine Mandelate



Benzeneacetic acid, α -hydroxy-, ($\pm$)-, compd. with 1,3,5,7-tetraazatricyclo[3.3.1.1^{3,7}]decane (1:1);
 Hexamethylenetetramine mono-($\pm$)-mandelate CAS RN[®]: 587-23-5; UNII: 695N30CINR.

DEFINITION

Methenamine Mandelate contains NLT 95.5% and NMT 102.0% of methenamine mandelate ($C_6H_{12}N_4 \cdot C_8H_8O_3$), and contains NLT 50.0% and NMT 53.0% of mandelic acid ($C_8H_8O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

ASSAY

PROCEDURE

Sample solution: Transfer 60 mg of Methenamine Mandelate 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: 95.5%–102.0% on the dried basis

OTHER COMPONENTS

CONTENT OF MANDELIC ACID

Sample solution: Transfer 90 mg to a 250-mL conical flask containing 50 mL of water. When the solution is complete, titrate the magnetically stirred solution.

Titrimetric system

Mode: Direct titration

Titrant: 0.05 N ceric ammonium nitrate VS

Endpoint detection: Potentiometric

Analysis: Titrate the *Sample solution* with *Titrant*, determining the endpoint potentiometrically. Each mL of 0.05 N ceric ammonium nitrate is equivalent to 3.804 mg of mandelic acid ($C_8H_8O_3$).

Acceptance criteria: 50.0%–53.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%
- [CHLORIDE AND SULFATE, Chloride\(221\)](#)

Sample: 1.0 g

Analysis: Dissolve the *Sample* in 10 mL of water, and add gradually 500 mg of anhydrous sodium carbonate. Evaporate to dryness, and ignite the residue at a dull-red heat. Add 20 mL of 2 N nitric acid, stir gently, and filter.

Acceptance criteria: 0.01%; the filtrate shows no more chloride than corresponds to 0.15 mL of 0.020 N hydrochloric acid.

• **SULFATE**

Sample: 0.20 g

Analysis: Dissolve the *Sample* in 10 mL of water. Add 5 drops of 3 N hydrochloric acid and 5 drops of barium chloride TS.

Acceptance criteria: No turbidity appears within 1 min.

SPECIFIC TESTS

• [Loss on Drying \(731\)](#)

Analysis: Dry over silica gel for 18 h.

Acceptance criteria: NMT 1.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Methenamine Mandelate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
METHENAMINE MANDELATE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-ADDC3589-6A29-4382-B238-6B2EE99D5F39_4_en-US

DOI: https://doi.org/10.31003/USPNF_M50900_04_01

DOI ref: [7s6cu](#)