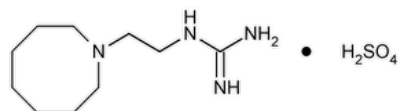


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-75C4BEDD-CBB7-4406-B6D2-76B7CEADF98F_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M36070_04_01
 DOI Ref: lz8du

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Guanethidine Monosulfate



$C_{10}H_{22}N_4 \cdot H_2SO_4$ 296.39

Guanidine, [2-(hexahydro-1(2H)-azocinyl)ethyl]-, sulfate (1:1);

[2-(Hexahydro-1(2H)-azocinyl)ethyl]guanidine sulfate (1:1) CAS RN®: 645-43-2; UNII: 5UBY8Y002G.

DEFINITION

Guanethidine Monosulfate contains NLT 97.0% and NMT 103.0% of guanethidine monosulfate ($C_{10}H_{22}N_4 \cdot H_2SO_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• B.

Sample solution: 2.5 mg dissolved in 10 mL of water

Analysis: To the *Sample solution* add 2 mL of a solution prepared by dissolving 500 mg of 1-naphthol, 3 g of sodium hydroxide, and 8 g of sodium carbonate in water to make 50 mL, and 1 mL of a solution of 2,3-butanedione (1 in 2000). Allow to stand at room temperature.

Acceptance criteria: An intense, pinkish-red color develops.

ASSAY

• PROCEDURE

Solution A: 10 mg/mL of sodium nitroferricyanide and 10 mg/mL of potassium ferricyanide in water

Standard solution: 1 mg/mL of [USP Guanethidine Monosulfate RS](#) in 1 N sulfuric acid

Sample solution: 1 mg/mL of Guanethidine Monosulfate in 1 N sulfuric acid

Blank: 1 N sulfuric acid

Instrumental conditions

Mode: UV-Vis

Analytical wavelength: Maximum absorbance at about 500 nm

Cell: 1 cm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Pipet 2 mL each of the *Standard solution*, *Sample solution*, and *Blank* into separate glass-stoppered, 40-mL centrifuge tubes. Add 10.0 mL of water to each tube. Add 10.0 mL of *Solution A*, and mix. Add 4.0 mL of 1 N sodium hydroxide to each tube, mix, and allow to stand for 20 min, accurately timed.

Calculate the percentage of guanethidine monosulfate ($C_{10}H_{22}N_4 \cdot H_2SO_4$) in the portion of Guanethidine Monosulfate taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Guanethidine Monosulfate RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Guanethidine Monosulfate in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

Analysis: Dry at 105° to constant weight.

Acceptance criteria: NMT 0.5%

- [pH \(791\)](#)

Sample solution: 20 mg/mL

Acceptance criteria: 4.7–5.7

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Guanethidine Monosulfate RS](#)

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

Topic/Question	Contact	Expert Committee
GUANETHIDINE MONOSULFATE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 45(6)

Current DocID: GUID-75C4BEDD-CBB7-4406-B6D2-76B7CEADF98F_4_en-US

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