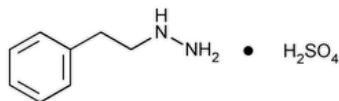


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Phenelzine Sulfate



$C_8H_{12}N_2 \cdot H_2SO_4$ 234.27

Hydrazine, (2-phenylethyl)-, sulfate (1:1);

Phenethylhydrazine sulfate (1:1) CAS RN®: 156-51-4; UNII: 2681D7P965.

DEFINITION

Phenelzine Sulfate contains NLT 98.0% and NMT 102.0% of phenelzine sulfate ($C_8H_{12}N_2 \cdot H_2SO_4$), calculated on the dried basis.

IDENTIFICATION

• **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K

• **B.**

Sample: Dissolve 100 mg of Phenelzine Sulfate in 5 mL of [water](#), render the solution alkaline with 1 N [sodium hydroxide](#), and add 1 mL of [alkaline cupric tartrate TS](#).

Acceptance criteria: A red to yellow-red precipitate is formed

• **C.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), *Chemical Identification Tests, Sulfate*

Sample solution: 1 in 10 solution of Phenelzine Sulfate in [water](#)

Acceptance criteria: Meets the requirements

ASSAY

Change to read:

• **PROCEDURE**

Solution A: About 6.8 g/L of [monobasic potassium phosphate](#) and about 2.16 g/L of [sodium 1-octanesulfonate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.0.

Mobile phase: [Methanol](#) and *Solution A* (40:60)

Standard solution: ▲0.26▲ (IRA 1-May-2023) mg/mL of [USP Phenelzine Sulfate RS](#) in *Mobile phase*

Sample solution: ▲0.26 mg/mL of Phenelzine Sulfate in *Mobile phase*▲ (IRA 1-May-2023)

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 210 nm

Column: 3.9-mm × 15-cm; ▲5-μm▲ (IRA 1-May-2023) packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 20 μL

▲**Run time:** NLT 2 times the retention time of phenelzine▲ (IRA 1-May-2023)

System suitability

Sample: *Standard solution*

Suitability requirements

▲ (IRA 1-May-2023)

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis**Samples:** *Standard solution* and *Sample solution*Calculate the percentage of phenelzine sulfate ($C_8H_{12}N_2 \cdot H_2SO_4$) in the portion of Phenelzine Sulfate taken:

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

 r_U = peak response of phenelzine from the *Sample solution* r_S = peak response of phenelzine from the *Standard solution* C_S = concentration of [USP Phenelzine Sulfate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Phenelzine Sulfate in the *Sample solution* (mg/mL)**Acceptance criteria:** 98.0%–102.0% on the dried basis**IMPURITIES**• **ORDINARY IMPURITIES (466).****Standard solution:** [Methanol](#) and [water](#) (50:50)**Sample solution:** [Methanol](#) and [water](#) (50:50)**Eluent:** [Acetone](#)[NOTE—Prewash the plate with *Eluent*, and dry.]**Visualization:** 1**Acceptance criteria:** Meets the requirements**Change to read:**• **LIMIT OF HYDRAZINE****Solution A:** 1% [monobasic ammonium phosphate](#) in [water](#)**Mobile phase:** [Methanol](#) and *Solution A* (75:25)**▲Standard stock solution A:** 0.1 mg/mL hydrazine prepared as follows. Dissolve about 42.0 mg of hydrazine sulfate, equivalent to about 10 mg of hydrazine, in [water](#) in a 100-mL volumetric flask, and sonicate for about 5 min. Dilute with [methanol](#) to volume.**Standard stock solution B:** 5.0 µg/mL of hydrazine from *Standard stock solution A* in [methanol](#)**System suitability solution:** 0.125 µg/mL of hydrazine and 0.129 mg/mL of [USP Phenelzine Sulfate RS](#) prepared as follows. Transfer about 25.8 mg of [USP Phenelzine Sulfate RS](#) to a 200-mL volumetric flask, add 50 mL of [methanol](#), and sonicate to dissolve. Add 5 mL of *Standard stock solution B* and 0.7 mL of [ammonium hydroxide](#) and shake. Add 0.5 mL of [salicylaldehyde](#) and shake by mechanical means for about 5 min. Dilute with [methanol](#) to volume, sonicate for about 2 min, and mix.**Standard solution:** 0.125 µg/mL of hydrazine prepared as follows. Transfer 5.0 mL of *Standard stock solution B* to a 200-mL volumetric flask, add 50 mL of [methanol](#) and 0.7 mL of [ammonium hydroxide](#), and shake. Add 0.5 mL of [salicylaldehyde](#) and shake by mechanical means for about 5 min. Dilute with [methanol](#) to volume, sonicate for about 2 min, and mix. ▲ (IRA 1-May-2023)**Sample solution:** ▲0.129 mg/mL of Phenelzine Sulfate prepared as follows. ▲ (IRA 1-May-2023) Transfer about 25.8 mg of Phenelzine Sulfate to a 200-mL volumetric flask, add about 50 mL of [methanol](#), and sonicate to dissolve. Add 0.7 mL of [ammonium hydroxide](#) and shake. Add 0.5 mL of [salicylaldehyde](#) and shake by mechanical means for about 5 min. Dilute with [methanol](#) to volume, sonicate for about 2 min, and mix.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 340 nm**Column:** 4.6-mm × 25-cm; 5-µm packing [L1](#)**▲Flow rate:** 1.5 mL/min ▲ (IRA 1-May-2023)**Injection volume:** 50 µL**▲Run time:** NLT 1.4 times the retention time of hydrazine derivative (salazine) ▲ (IRA 1-May-2023)**System suitability****Samples:** ▲*System suitability solution* ▲ (IRA 1-May-2023) and *Standard solution*

[NOTE—The relative retention times for salicylaldehyde, phenelzine ▲ (IRA 1-May-2023) derivative, and ▲hydrazine derivative (salazine) ▲ (IRA 1-May-2023) are about ▲0.16, 0.56, ▲ (IRA 1-May-2023) and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.25 between phenelzine $\blacktriangle$ derivative $\blacktriangle$ (IRA 1-May-2023) and $\blacktriangle$ hydrazine derivative (salazine), *System suitability solution* $\blacktriangle$ (IRA 1-May-2023)

Relative standard deviation: NMT 7%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of hydrazine $\blacktriangle$ (N₂H₄) $\blacktriangle$ (IRA 1-May-2023) in the portion of Phenelzine Sulfate taken:

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

r_U = peak response of $\blacktriangle$ hydrazine derivative (salazine) $\blacktriangle$ (IRA 1-May-2023) from the *Sample solution*

r_S = peak response of $\blacktriangle$ hydrazine derivative (salazine) $\blacktriangle$ (IRA 1-May-2023) from the *Standard solution*

C_S = concentration of hydrazine $\blacktriangle$ $\blacktriangle$ (IRA 1-May-2023) in the *Standard solution* (mg/mL)

C_U = concentration of Phenelzine Sulfate in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.1%

SPECIFIC TESTS

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

Analysis: Dry at 80° for 2 h over silica gel, at a pressure not exceeding 5 mm of mercury.

Acceptance criteria: NMT 1.0%

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

Sample solution: 10 mg/mL of Phenelzine Sulfate in [water](#)

Acceptance criteria: 1.4–1.9

- [Melting Range or Temperature \(741\)](#).

Acceptance criteria: 164°–168°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers. Protect from heat and light.

- [USP Reference Standards \(11\)](#).

[USP Phenelzine Sulfate RS](#)

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

Topic/Question	Contact	Expert Committee
PHENELZINE SULFATE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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