

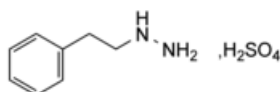


Edition: BP 2025 (Ph. Eur. 11.6 update)

Phenelzine Sulfate

[General Notices](#)

Phenelzine Sulphate



234.3 156-51-4

Action and use

Monoamine oxidase inhibitor; antidepressant.

Preparation

[Phenelzine Tablets](#)

DEFINITION

Phenelzine Sulfate is phenethylhydrazine hydrogen sulfate. It contains not less than 98.0% and not more than 102.0% of $C_8H_{12}N_2 \cdot H_2SO_4$, calculated with reference to the dried substance.

CHARACTERISTICS

A white powder or pearly platelets.

Freely soluble in [water](#); practically insoluble in [ethanol \(96%\)](#) and in [ether](#).

IDENTIFICATION

- A. The [light absorption](#), [Appendix II B](#), in the range 230 to 350 nm of a 0.1% w/v solution in 0.05M [sulfuric acid](#) exhibits three well-defined maxima, at 252, 258 and 263 nm. The *absorbances* at the maxima are about 0.62, about 0.77 and about 0.58, respectively.
- B. Dissolve 0.1 g in 5 mL of [water](#), make alkaline with 5M [sodium hydroxide](#) and add 1 mL of [cupri-tartaric solution](#) R1. A red precipitate is produced.
- C. Yields reaction A characteristic of [sulfates](#), [Appendix VI](#).

TESTS

Melting point

164° to 168°, [Appendix V A](#).

Loss on drying

When dried over [phosphorus pentoxide](#) at a pressure not exceeding 0.7 kPa for 24 hours, loses not more than 1.0% of its weight. Use 1 g.

Sulfated ash

Not more than 0.1%, [Appendix IX A](#).

ASSAY

Carry out the method for [liquid chromatography, Appendix III D](#), using the following solutions.

- (1) 0.026% w/v of the substance to be examined in the mobile phase.
- (2) 0.026% w/v [phenelzine sulfate BPCRS](#) in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

- (a) A stainless steel column (15 cm × 3.9 mm) packed with [octadecylsilyl silica gel for chromatography](#) (5 µm) (Waters Symmetry C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 1.0 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 210 nm.
- (f) Inject 20 µL of each solution.

MOBILE PHASE

40 volumes of [methanol R2](#) and 60 volumes of a solution of 0.216% w/v [sodium octanesulfonate](#) and 0.68% w/v [potassium dihydrogen phosphate](#) previously adjusted to pH 3.0 with [orthophosphoric acid](#).

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the [symmetry factor](#) of the principal peak is between 0.8 and 2.0.

DETERMINATION OF CONTENT

Calculate the content of $C_8H_{12}N_2 \cdot H_2SO_4$ in the substance being examined using the declared content of $C_8H_{12}N_2 \cdot H_2SO_4$ in [phenelzine sulfate BPCRS](#).

STORAGE

Phenelzine Sulfate should be protected from light.