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Phenelzine Sulfate Tablets

» Phenelzine Sulfate Tablets contain an amount of phenelzine sulfate ($C_8H_{12}N_2 \cdot H_2SO_4$) equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of phenelzine ($C_8H_{12}N_2$).

Packaging and storage—Preserve in tight containers, protected from heat and light.

USP Reference standards ⟨11⟩—

USP Phenelzine Sulfate RS

Identification—Extract a portion of powdered Tablets, equivalent to about 30 mg of phenelzine, with 10 mL of water, and filter: the filtrate responds to *Identification* tests *B* and *C* under *Phenelzine Sulfate.*

Disintegration ⟨701⟩—Place 1 tablet in each of the 6 tubes of the basket and, if the tablets have a soluble external coating, immerse the basket in water at room temperature for 5 minutes. Then add a disk to each tube, and operate the apparatus, using simulated gastric fluid TS maintained at 37 ± 2° as the immersion fluid. After 30 minutes of operation in simulated gastric fluid TS, lift the basket from the fluid, and observe the tablets. If the tablets have not disintegrated completely, substitute simulated intestinal fluid TS maintained at 37 ± 2° as the immersion fluid. Continue the test for a total period of time, including previous exposure to water and simulated gastric fluid TS, of 1 hour and 30 minutes. Lift the basket from the fluid, and observe the tablets: all of the tablets have disintegrated completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not less than 16 of the total 18 tablets tested disintegrate completely.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Ion-pair solution—Dissolve about 6.8 g of monobasic potassium phosphate and about 2.16 g of sodium 1-octanesulfonate in 1000 mL of water, and mix. Adjust with phosphoric acid to a pH of 3.0, and filter.

Mobile phase—Prepare a filtered and degassed mixture of *Ion-pair solution* and methanol (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Phenelzine Sulfate RS in *Mobile phase*, and dilute quantitatively, and stepwise if necessary, with *Mobile phase* to obtain a solution having a known concentration of about 258 µg per mL.

Assay preparation—Transfer not less than 20 Tablets to a suitable container, add about 300 mL of *Mobile phase*, and homogenize until dissolved. Transfer this solution to a 500-mL volumetric flask, dilute with *Mobile phase* to volume, mix, centrifuge, and filter, discarding the first 5 mL of the filtrate. Transfer a portion of the filtrate, equivalent to about 12.9 mg of phenelzine sulfate, to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 210-nm detector and a 3.9-mm × 15-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the column efficiency is not less than 3000 theoretical plates, the tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of phenelzine ($C_8H_{12}N_2$) in the *Assay preparation* by the formula:

$$(136.20/234.27)(50C)(r_U/r_S)$$

in which 136.20 and 234.27 are the molecular weights of phenelzine and phenelzine sulfate, respectively, C is the concentration, in µg per mL, of USP Phenelzine Sulfate RS in the *Standard preparation*, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

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