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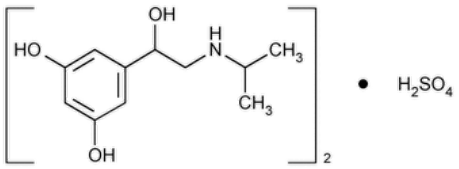
Metaproterenol Sulfate



$(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$ 520.59

1,3-Benzenediol, 5-[1-hydroxy-2-(1-methylethyl)amino] ethyl-, (±)-, sulfate (2:1) (salt).

(±)-3,5-Dihydroxy-α-[(isopropylamino)methyl]benzyl alcohol sulfate (2:1) CAS RN®: 5874-97-5; UNII: GJ20H50YF0.

» Metaproterenol Sulfate contains not less than 98.0 percent and not more than 102.0 percent of $(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$, calculated on the anhydrous, isopropyl alcohol-free, and methanol-free basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Metaproterenol Sulfate RS

Identification—

A: *Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197K*.

B: To a solution of 10 mg in 1 mL of water add 1 drop of ferric chloride TS: a violet color is produced.

C: It responds to the tests for *Sulfate* ⟨191⟩.

D: The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for metaproterenol, the retention time of which corresponds with that exhibited in the chromatogram of the *Standard preparation* obtained as directed in the *Assay*.

pH ⟨791⟩: between 4.0 and 5.5, in a solution containing 100 mg per mL.

Water Determination, *Method I* ⟨921⟩: not more than 2.0%.

Residue on Ignition ⟨281⟩: not more than 0.1%.

Change to read:

▲**Iron** ⟨241⟩, *Procedures, Procedure 1*▲ (CN 1-Jun-2023) —Dissolve 2.0 g in 45 mL of water, add 2 mL of hydrochloric acid, and mix: the limit is 5 ppm.

Limit of metaproterenone sulfate—Its absorptivity (see *Ultraviolet-Visible Spectroscopy* ⟨857⟩) at 328 nm, determined in an aqueous solution containing 9.0 mg per mL, is not more than 0.009 (0.1%).

Isopropyl alcohol and methanol—

Isopropyl alcohol standard solution—Transfer about 0.3 g of isopropyl alcohol, accurately weighed, to a 100-mL volumetric flask containing about 10 mL of water, dilute with water to volume, and mix. Pipet 10 mL of the resulting solution into a 100-mL volumetric flask, add about 85 mL of pyridine, mix, and allow to stand for 1 hour. Dilute with pyridine to volume, and mix. Pipet 5 mL of this solution to a 50-mL volumetric flask, dilute with pyridine to volume, and mix. The solution so obtained contains about 30 µg of isopropyl alcohol per mL.

Methanol standard solution—Prepare as directed for *Isopropyl alcohol standard solution*, using about 0.1 g of methanol, accurately weighed. The resulting solution contains about 10 µg of methanol per mL.

Test preparation—Transfer about 1 g of Metaproterenol Sulfate, accurately weighed, to a 100-mL volumetric flask, dissolve in about 2 mL of water, dilute with pyridine to volume, and mix.

Chromatographic system—The gas chromatograph is equipped with a flame-ionization detector and contains a 2-m × 2-mm column packed with 0.1% liquid phase G25 on 80- to 100-mesh support S7. The injection port is maintained at a temperature of about 150°; the column is programmed for 2 minutes at 40°, to increase at a rate of about 15° per minute to 200°, and for 10 minutes at 200°; the detector is maintained at about 250°; and helium is used as the carrier gas at a flow rate of about 15 mL per minute.

Procedure—Inject equal volumes (about 2 µL) of the *Test preparation*, the *Isopropyl alcohol standard solution*, and the *Methanol standard solution* successively into the gas chromatograph. Measure the responses of the isopropyl alcohol peak and the methanol peak in each chromatogram. Determine the quantities, in mg, of isopropyl alcohol and methanol in the portion of Metaproterenol Sulfate taken by the formula:

$$0.1C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of isopropyl alcohol or methanol in the *Isopropyl alcohol standard solution* or the *Methanol*

standard solution; and r_U and r_S are the responses of the respective analytes in the *Test preparation* and of the corresponding *Isopropyl alcohol standard solution* or *Methanol standard solution:* not more than 0.3% of isopropyl alcohol and not more than 0.1% of methanol are found.

Assay—

Mobile phase—Dissolve 11.9 g of anhydrous dibasic sodium phosphate in water to make 1000 mL of solution, and mix (*Solution A*). Dissolve 9.1 g of monobasic potassium phosphate in water to make 1000 mL of solution, and mix (*Solution B*). Mix 735 mL of *Solution A* and 140 mL of *Solution B*, add 125 mL of methanol, and mix. Filter and degas this solution before use.

Standard preparation—Dissolve an accurately weighed quantity of USP Metaproterenol Sulfate RS in 0.01 N hydrochloric acid to obtain a solution having a known concentration of about 2 mg per mL.

Assay preparation—Transfer about 100 mg of Metaproterenol Sulfate, accurately weighed, to a 50-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 278-nm detector and a 4.6-mm × 5-cm guard column that contains packing L7 and a 4.6-mm × 25-cm analytical column that contains 10-µm packing L7. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 500 theoretical plates, the tailing factor for the analyte peak is not more than 3.0, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 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 mg, of $(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$ in the portion of Metaproterenol Sulfate taken by the formula:

$$50C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Metaproterenol Sulfate RS in the *Standard preparation*, and r_U and r_S are the peak responses from the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METAPROTERENOL SULFATE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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