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Metaproterenol Sulfate Tablets

» Metaproterenol Sulfate Tablets contain not less than 92.0 percent and not more than 108.0 percent of the labeled amount of metaproterenol sulfate [$(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$].

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

USP Reference standards ⟨11⟩—
USP Metaproterenol Sulfate RS

Change to read:

Identification—

A: Powder a number of Tablets, equivalent to about 100 mg of metaproterenol sulfate, add 10 mL of water, stir for about 3 minutes, and centrifuge. Use the clear solution so obtained as the *Test solution*. Dissolve a suitable quantity of USP Metaproterenol Sulfate RS in water to obtain a Standard solution having a concentration of 10 mg per mL. Apply separate 10-µL portions of the *Test solution* and the Standard solution to a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. ▲Allow the spots to dry, and develop the chromatogram in a solvent system consisting of the upper layer of a freshly prepared mixture of butyl alcohol, water, and formic acid (50:25:7) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by examination under short-wavelength UV light:▲ (ERR 1-Mar-2023) the R_F value of the principal spot obtained from the *Test solution* corresponds to that obtained from the Standard solution.

B: Mix a quantity of powdered Tablets, equivalent to about 20 mg of metaproterenol sulfate, with 5 mL of water, and filter: the filtrate responds to the tests for *Sulfate* ⟨191⟩.

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

Dissolution ⟨711⟩—
Medium: water; 500 mL.
Apparatus 2: 50 rpm.
Time: 30 minutes.
Procedure—Determine the amount of $(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 276 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Metaproterenol Sulfate RS in the same *Medium*.
Tolerances—Not less than 70% *(Q)* of the labeled amount of $(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$ is dissolved in 30 minutes.

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

Assay—

Mobile phase, Standard preparation, and *Chromatographic system*—Prepare as directed in the *Assay* under *Metaproterenol Sulfate*.
Assay preparation—Transfer 20 Tablets to a 500-mL conical flask. Add an accurately measured volume of 0.01 N hydrochloric acid sufficient to yield a solution containing about 2 mg of metaproterenol sulfate per mL, shake by mechanical means for 30 minutes, and filter. Use the filtrate so obtained as the *Assay preparation*.
Procedure—Proceed as directed for *Procedure* in the *Assay* under *Metaproterenol Sulfate*. Calculate the quantity, in mg, of metaproterenol sulfate [$(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4$] in each Tablet taken by the formula:

$$(CV/20)(r_U/r_S)$$

in which V is the volume, in mL, of 0.01 N hydrochloric acid added; and C, r_U, and r_S are as defined therein.

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

Topic/Question	Contact	Expert Committee
METAPROTERENOL SULFATE TABLETS	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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