https://trungtamthuoc.com/

Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Mar-2023
Document Type: USP Monographs
DocId: GUID-3F99E96A-A3D2-4E36-8A5D-C5188A0D89B0_2_en-US
DOI: https://doi.org/10.31003/USPNF_M49720_02_01
DOI Ref: t509n

© 2025 USPC
Do not distribute

Metaproterenol Sulfate Oral Solution

» Metaproterenol Sulfate Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of metaproterenol sulfate $[(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4]$.

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

USP Reference standards ⟨11⟩—
USP Metaproterenol Sulfate RS

Change to read:

Identification—

A: Transfer a portion of Oral Solution, equivalent to about 10 mg of metaproterenol sulfate, to a separator, and extract with four 30-mL portions of ether, discarding the ether extracts. Apply 10 µL of the extracted portion of Oral Solution to the lower right corner of a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture, and allow to dry. Develop the chromatogram in a solvent system consisting of the lower layer of a well-shaken mixture of dioxane, methylene chloride, alcohol, and ammonium hydroxide (4:4:1:1). Allow the solvent front to move about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and dry in vacuum at 35° to 40° for 30 minutes. Rotate the plate 90°. At a point about four-fifths of the distance between the initial application of the Oral Solution extract and the solvent front, apply 10 µL of a Standard solution of USP Metaproterenol Sulfate RS in water containing about 2 mg per mL. ▲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 Oral Solution corresponds to that obtained from the Standard solution.

B: The retention time of the major peak for metaproterenol in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

pH ⟨791⟩**:** between 2.5 and 4.0, in a solution obtained by mixing 1 volume of Oral Solution and 4 volumes of water.

Assay—

Mobile phase—Mix 10 mL of formic acid and water to make 1000 mL of solution. Filter and degas this solution before use. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Metaproterenol Sulfate RS in water to obtain a solution having a known concentration of about 0.2 mg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 20 mg of metaproterenol sulfate, to a 100-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 278-nm detector, a 4.6-mm × 5-cm guard column that contains packing L2, and a 3.9-mm × 30-cm analytical column that contains packing L1. [Note—After use, rinse the analytical column with water and store with water in it.] The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* 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 100 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 metaproterenol sulfate $[(C_{11}H_{17}NO_3)_2 \cdot H_2SO_4]$ in each mL of the Oral Solution taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Metaproterenol Sulfate RS in the *Standard preparation; V* is the volume, in mL, of Oral Solution taken; 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.

OFFICIAL

www.webofpharma.com

https://trungtamthuoc.com/

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 28(2)

Current DocID: GUID-3F99E96A-A3D2-4E36-8A5D-C5188A0D89B0_2_en-US

DOI: https://doi.org/10.31003/USPNF_M49720_02_01

DOI ref: t509n

OFFICIAL