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Methazolamide Tablets

» Methazolamide Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of methazolamide ($C_5H_8N_4O_3S_2$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Methazolamide RS

Identification—

A: Extract a quantity of finely powdered Tablets, equivalent to about 250 mg of methazolamide, with about 50 mL of acetone. Filter, and add solvent hexane until a heavy white precipitate is formed. Collect the solid on a filter, and dry: the IR absorption spectrum of a potassium bromide dispersion of the methazolamide so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Methazolamide RS.

B: Dissolve about 100 mg of the dried solid obtained in *Identification* test *A* in 5 mL of 1 N sodium hydroxide, and add 5 mL of a mixture of 1 g of hydroxylamine hydrochloride and 500 mg of cupric sulfate in 100 mL of water. Heat the solution on a steam bath for 15 minutes: the solution turns dark amber, then a black precipitate is formed.

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

Dissolution ⟨711⟩—
Medium: pH 4.5 acetate buffer, prepared by mixing 2.99 g of sodium acetate and 1.66 mL of glacial acetic acid with water to obtain 1000 mL of a solution having a pH of 4.5; 900 mL.
Apparatus 2: 75 rpm.
Time: 45 minutes.
Procedure—Determine the amount of $C_5H_8N_4O_3S_2$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 252 nm of filtered portions of the solution under test, suitably diluted with pH 4.5 acetate buffer, in comparison with a Standard solution having a known concentration of USP Methazolamide RS in the same *Medium*.
Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_5H_8N_4O_3S_2$ is dissolved in 45 minutes.

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

Assay—
pH 2.5 Buffer—Transfer 16.8 mL of dibutylamine to a beaker containing 70 mL of water. Adjust with phosphoric acid to a pH of 2.5, dilute with water to 100 mL, and mix.
Mobile phase—Prepare a mixture of water, methanol, and *pH 2.5 Buffer* (375:15:6). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).
pH 4.5 Acetate buffer—Dissolve 2.99 g of sodium acetate and 1.66 mL of glacial acetic acid in water, dilute with water to 1000 mL, and mix. Adjust, if necessary, with glacial acetic acid or sodium hydroxide to a pH of 4.5.
Standard preparation—Dissolve an accurately weighed quantity of USP Methazolamide RS in methanol to obtain a solution having a concentration of about 0.5 mg per mL. Dilute this solution quantitatively, and stepwise if necessary, with *pH 4.5 Acetate buffer* to obtain a solution having a known concentration of about 50 µg per mL.
Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of methazolamide, to a 250-mL volumetric flask, add 65 mL of *pH 4.5 Acetate buffer*, and sonicate to dissolve. Add 65 mL of methanol, and sonicate again until dissolved. Dilute with *pH 4.5 Acetate buffer* to volume, mix, and filter. Dilute an accurately measured volume of the filtrate with *pH 4.5 Acetate buffer* to obtain a solution having a concentration of about 50 µg of methazolamide per mL.
Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 252-nm detector and an 8-mm × 10-cm column that contains packing L10. 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 is not more than 1.5; and the relative standard deviation for replicate injections is not more than 3.0%.

Procedure—Separately inject equal volumes (about 25 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of methazolamide ($C_5H_8N_4O_3S_2$) in the portion of Tablets taken by the formula:

$$C(r_U/r_S)$$

in which C is the concentration, in µg per mL, of USP Methazolamide 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.

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

Topic/Question	Contact	Expert Committee
METHAZOLAMIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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

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