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Homatropine Methylbromide Tablets

» Homatropine Methylbromide Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{17}H_{24}BrNO_3$.

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

USP Reference standards ⟨11⟩—
USP Homatropine Methylbromide RS

Identification—Shake a quantity of finely powdered Tablets, equivalent to about 10 mg of homatropine methylbromide, with 15 mL of a mixture of equal volumes of methanol and water for 10 minutes, and filter. Evaporate the filtrate on a steam bath to dryness, and dry at 105° for 1 hour. The residue of homatropine methylbromide so obtained melts between 190° and 198° (see *Class I* under *Melting Range or Temperature* ⟨741⟩), the temperature at which distinct liquefaction of the specimen is first observed being taken as the beginning of melting.

Dissolution ⟨711⟩—
Medium: water; 900 mL.
Apparatus 2: 50 rpm.
Time: 45 minutes.
Procedure—Determine the amount of $C_{17}H_{24}BrNO_3$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 258 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 Homatropine Methylbromide RS in the same medium.
Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{17}H_{24}BrNO_3$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.
Procedure for content uniformity—
Standard preparation—Transfer about 25 mg of USP Homatropine Methylbromide RS, accurately weighed, to a 50-mL volumetric flask, add water to volume, and mix. Transfer 10.0 mL of this solution to a second 50-mL volumetric flask, dilute with water to volume, and mix. The concentration of USP Homatropine Methylbromide RS in the *Standard preparation* is about 100 µg per mL.
Test preparation—Transfer 1 finely powdered Tablet to a volumetric flask, suitably sized such that when the specimen is diluted to volume, the concentration is equivalent to about 100 µg of homatropine methylbromide per mL. Add water to about one-half of the volume of the flask, shake for 10 minutes, dilute with water to volume, mix, and filter, discarding the first 10 mL of filtrate. Use the subsequent filtrate as directed in the *Procedure*.
Procedure—Transfer 2.0 mL each of the *Standard preparation* and the *Test preparation* to separate glass-stoppered, 50-mL flasks. To each flask, add 0.1 mL of sodium hydroxide solution (1 in 10), and heat in a water bath at 80° for 15 minutes. Cool to room temperature, add 2.0 mL of 0.2 M ceric ammonium sulfate in 1 N sulfuric acid, and mix. To each flask, add 20.0 mL of *n*-hexane, and shake for 15 minutes. Decant the hexane layers into separate 1-cm cells, and concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 242 nm, with a suitable spectrophotometer, using *n*-hexane as the blank. Calculate the quantity, in mg, of $C_{17}H_{24}BrNO_3$ in the Tablet by the formula:

$$(TC/D)(A_U/A_S)$$

in which T is the labeled quantity, in mg, of homatropine methylbromide in the Tablet; C is the concentration, in µg per mL, of USP Homatropine Methylbromide RS in the *Standard preparation*; D is the concentration, in µg per mL, of the *Test preparation*, based upon the labeled quantity per Tablet and the extent of dilution; and A_U and A_S are the absorbances of the solutions from the *Test preparation* and the *Standard preparation*, respectively.

Assay—
Standard preparation—Transfer about 25 mg of USP Homatropine Methylbromide RS, accurately weighed, to a 50-mL volumetric flask, dissolve in water, dilute with water to volume, and mix.
Assay preparation—Weigh and finely powder not less than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 12.5 mg of homatropine methylbromide, and shake with 10 mL of water at frequent intervals during 30 minutes. Filter under reduced pressure through

a sintered-glass crucible into a test tube placed in the suction flask under the filtering funnel, and wash under suction with several small portions of water. Transfer the contents of the test tube to a 25-mL volumetric flask, dilute with water to volume, and mix. *Procedure*—Transfer 10.0 mL each of the *Standard preparation* and the *Assay preparation* to separate test tubes, to each add 1 mL of 5 N sulfuric acid and 2 mL of ammonium reineckate TS, shake gently but well, and allow to stand for 1 hour. Filter through a sintered-glass crucible with suction, using portions of the filtrate to transfer the precipitate completely to the filter, and wash it with three 2-mL portions of ice-cold water. Completely dissolve the precipitate by pouring over it 1-mL portions of acetone with the application of suction, receiving the solution in a 10-mL volumetric flask, add acetone to volume, and mix. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 525 nm, with a suitable spectrophotometer, using acetone as the blank. Calculate the quantity, in mg, of $C_{17}H_{24}BrNO_3$ in the portion of Tablets taken by the formula:

$$0.025C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Homatropine Methylbromide RS in the *Standard preparation*; and A_U and A_S are the absorbances of the solutions 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
HOMATROPINE METHYLBROMIDE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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