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Mecamylamine Hydrochloride Tablets

» Mecamylamine Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of mecamylamine hydrochloride ($C_{11}H_{21}N \cdot HCl$).

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—
USP Mecamylamine Hydrochloride RS

Identification—

A: To a quantity of powdered Tablets, equivalent to about 75 mg of mecamylamine hydrochloride, add 50 mL of chloroform, and triturate the mixture for 5 minutes. Filter, and evaporate the filtrate on a steam bath with the aid of a current of air to dryness: the IR absorption spectrum of a potassium bromide dispersion of a portion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Mecamylamine Hydrochloride RS.

B: A portion of the residue obtained in *Identification* test *A* responds to the tests for *Chloride ⟨191⟩*.

Dissolution ⟨711⟩—

Medium: water; 750 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Determine the amount of $C_{11}H_{21}N \cdot HCl$ dissolved using the following procedure.

Diluent—Prepare a solution of triethylamine in alcohol (1:100).

Internal standard solution—Prepare a solution of biphenyl in *Diluent* having a concentration of 82.5 µg per mL.

Standard solution—Prepare a solution of USP Mecamylamine Hydrochloride RS and biphenyl in *Diluent* having concentrations of 8.25 µg per mL of each.

Test solution—[Note—Condition the solid-phase extraction column specified in this procedure in the following manner. Wash the column with 5 mL of water, then with 5 mL of *Diluent*, and finally with two 5-mL portions of water.] Transfer by pipetting 25.0 mL of the solution under test through a freshly conditioned solid-phase extraction column containing L1 packing with a sorbent-mass to column volume ratio of 360 mg per 5 mL, or equivalent. Wash the pipet and the solid-phase extraction column with two 5-mL portions of water. Discard the filtrate. Elute the solid-phase extraction column with two 4-mL portions of *Diluent*, and collect the eluate in a 10-mL volumetric flask containing 1.0 mL of *Internal standard solution*. Dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The gas chromatograph is equipped with a flame-ionization detector, a splitless injection system, and a 0.53-mm × 30-m analytical column coated with a 1-5-µm layer of phase G27. The carrier gas is helium at a flow rate of 5.2 mL per minute. The detector and column temperatures are maintained at 250° and 150°, respectively. Chromatograph replicate injections of the *Standard solution*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 4000 theoretical plates, the tailing factor is not more than 2, and the relative standard deviation is not more than 2.0%.

Procedure—Separately inject equal volumes (about 2 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the amount in mg, of $C_{11}H_{21}N \cdot HCl$ dissolved by the formula:

$$0.3C(R_U/R_S)$$

in which C is the concentration, in µg per mL, of USP Mecamylamine Hydrochloride RS in the *Standard solution*; and R_U and R_S are the peak response ratios of the mecamylamine hydrochloride peak to the internal standard peak obtained from the *Test solution* and *Standard solution*, respectively.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{11}H_{21}N \cdot HCl$ is dissolved in 30 minutes.

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

Procedure for content uniformity—Place 1 Tablet in the digestion flask, and proceed as directed under *Nitrogen Determination, Method II ⟨461⟩*. Each mL of 0.01 N sulfuric acid is equivalent to 2.038 mg of mecamylamine hydrochloride.

Assay—Weigh and finely powder not fewer than 30 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 50 mg of mecamylamine hydrochloride, to a glass-stoppered, 125-mL conical flask. Add about 25 mL of water, insert the stopper in the flask, and shake by mechanical means for 20 minutes. Transfer the contents of the flask to a 250-mL separator with the aid of small portions of water. Add 1 mL of 1 N sodium hydroxide and 5 g of sodium chloride, and extract the mixture successively with two 50-mL and three 25-mL portions of ether. Wash the combined ether extracts with three 10-mL portions of water, and wash, in turn, the combined water washes with a 10-mL portion of ether, adding it to the washed combined ether extracts. Transfer the ether phase to a 250-mL conical flask containing 25.0 mL of 0.02 N sulfuric acid VS, and evaporate the ether on a steam bath. Cool the solution, add methyl red TS, and titrate the excess acid with 0.02 N sodium hydroxide VS. Each mL of 0.02 N sulfuric acid is equivalent to 4.075 mg of mecamylamine hydrochloride ($C_{11}H_{21}N \cdot HCl$).

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

Topic/Question	Contact	Expert Committee
MECAMYLAMINE HYDROCHLORIDE 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

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