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Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2022
Document Type: USP Monographs
DocId: GUID-392ED4EF-6989-492D-88C4-EA3E54013465_5_en-US
DOI: https://doi.org/10.31003/USPNF_M47670_05_01
DOI Ref: 84kpm

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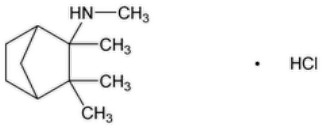
# Mecamylamine Hydrochloride



• HCl

$C_{11}H_{21}N \cdot HCl$ 203.75

Bicyclo[2.2.1]heptan-2-amine, *N*,2,3,3-tetramethyl-, hydrochloride.

*N*,2,3,3-Tetramethyl-2-norbornanamine hydrochloride CAS RN®: 826-39-1; UNII: 4956DJR58O.

» Mecamylamine Hydrochloride contains not less than 98.0 percent and not more than 100.5 percent of $C_{11}H_{21}N \cdot HCl$, calculated on the dried basis.

**Packaging and storage**—Preserve in tight containers.

***Change to read:***

**USP Reference standards** ⟨11⟩—

USP Mecamylamine Hydrochloride RS

USP Mecamylamine Related Compound A RS

▲*N*,1,7,7-Tetramethylbicyclo[2.2.1]heptan-2-amine hydrochloride.

$C_{11}H_{21}N \cdot HCl$ 203.75▲ (ERR 1-May-2022)

**Identification**—

**A:** *Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197K*.

**B:** It responds to the tests for *Chloride* ⟨191⟩.

**Acidity**—Dissolve 5.0 g in 100 mL of methanol, and titrate potentiometrically with 0.10 N alcoholic potassium hydroxide to an apparent pH of 5.5, using a calomel-glass electrode system and a potentiometer previously standardized with pH 5.0 neutralized phthalate buffer (see *Solutions* in the section *Reagents, Indicators, and Solutions*): after correction for the volume of alkali consumed by 100 mL of methanol, not more than 0.55 mL of 0.10 N alcoholic potassium hydroxide is required.

**Loss on drying** ⟨731⟩—Dry it at a pressure not exceeding 5 mm of mercury at 105° for 1 hour: it loses not more than 1.0% of its weight.

**Residue on ignition** ⟨281⟩: not more than 0.5%.

**Limit of residual solvents**—

*Diluent*—Prepare a mixture of dimethyl sulfoxide and water (2:1).

*Internal standard solution*—Prepare a solution of absolute alcohol in *Diluent* having a known concentration of about 15 µL per mL.

*Standard stock solution*—Transfer 50 mL of the *Diluent* to a 100-mL volumetric flask, add 0.64 mL of isopropyl alcohol, dilute with *Diluent* to volume, and mix.

*Standard solution*—Pipet 1.0 mL of the *Standard stock solution* into a 25-mL volumetric flask, dilute with *Diluent* to volume, and mix (*Solution 1*). Transfer about 500 mg of sodium chloride, accurately weighed, to a headspace vial, add 1.5 mL of *Solution 1* and 1.5 mL of the *Internal standard solution*, and mix.

*Test solution*—Transfer about 150 mg of Mecamylamine Hydrochloride, accurately weighed, to a headspace vial, add about 500 mg of sodium chloride, 1.5 mL of *Diluent*, and 1.5 mL of the *Internal standard solution*, and mix.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector and a 0.53-mm × 30-m capillary column whose internal wall is coated with a 1.0-µm film of liquid phase G16. This column is joined with a 0.53-mm × 25-m capillary column whose internal wall is coated with a 5.0-µm film of liquid phase G1. The G16 column is connected to the detector, and the G1 column is connected to the injector. The injection port temperature is maintained at about 100°; the detector temperature is maintained at about 210°; and the column temperature is maintained at 50° for 10 minutes, then increased at a rate of 5° per minute to 110°, then increased at a rate of 30° per minute to 210°, and maintained for 5 minutes at 210°. Nitrogen is used as the carrier gas, flowing at a rate of about 6.5 mL per minute. The split flow is 15 mL per minute.

*Procedure*—Allow the *Standard solution*, the *Internal standard solution*, and the *Test solution* to stand for 20 minutes at 90°. Separately inject equal volumes (about 1 mL) of the headspace of the *Standard solution*, the *Internal standard solution*, and the *Test solution* into the gas chromatograph, record the chromatograms, and measure the peak responses of the internal standard and isopropyl alcohol. Calculate the quantity, in ppm, of isopropyl alcohol in the portion of Mecamylamine Hydrochloride taken by the formula:

$$150(R_U)(W_S)/(R_S)(W_U)$$

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in which $W_S$ is the amount, in ppm, of isopropyl alcohol in the *Standard solution;* $W_U$ is the weight, in mg, of Mecamylamine Hydrochloride taken to prepare the *Test solution;* and $R_U$ and $R_S$ are the peak response ratios of isopropyl alcohol to the internal standard obtained from the *Test solution* and the *Standard solution*, respectively: not more than 2000 ppm of isopropyl alcohol is found.

**Related compounds**—

*Internal standard solution*—Proceed as directed in the *Assay*.

*Solution 1*—Prepare a solution of *dl*-camphene and USP Mecamylamine Related Compound A RS in the *Internal standard solution* containing 625 µg of each per mL.

*System suitability solution*—Transfer about 125 mg of USP Mecamylamine Hydrochloride RS, accurately weighed, to a 50-mL volumetric flask, add 1 mL of *Solution 1*, dilute with *Internal standard solution* to volume, and mix.

*Test solution*—Use the *Assay preparation*.

*Chromatographic system*—Prepare as directed in the *Assay*. Chromatograph the *System suitability solution*, and record peak responses as directed for *Procedure:* the resolution, *R,* between the mecamylamine and mecamylamine related compound A is not less than 5; the column efficiency is not less than 4000 theoretical plates; the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Inject a volume (about 1 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure all the peak responses. Calculate the percentage of each impurity in the portion of Mecamylamine Hydrochloride taken by the formula:

$$100(r_i/r_s)$$

in which $r_i$ is the peak response for each impurity; and $r_s$ is the sum of the responses for all the peaks: not more than 0.5% of mecamylamine related compound A is found; not more than 0.5% of *dl*-camphene is found; and not more than 1.0% of total impurities is found.

**Chloride content**—Dissolve about 500 mg, accurately weighed, in 5 mL of water. Add 5 mL of glacial acetic acid, 50 mL of methanol, and 1 drop of eosin Y TS, and titrate with 0.1 N silver nitrate VS. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of Cl: the content is between 17.0% and 17.8%.

**Assay**—

*Internal standard solution*—Transfer about 600 mg of sodium hydroxide pellets to a 1 L volumetric flask, dissolve in about 800 mL of methanol. Add an accurately weighed quantity of about 1.7 g of biphenyl to the flask, and dilute with methanol to volume.

*Standard preparation*—Dissolve an accurately weighed quantity of USP Mecamylamine Hydrochloride RS in *Internal standard solution*, and dilute with *Internal standard solution*, quantitatively and stepwise if necessary, to obtain a solution having a known concentration of about 2.5 mg per mL.

*Assay preparation*—Transfer about 125 mg of Mecamylamine Hydrochloride, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with *Internal standard solution* to volume, and mix.

*Chromatographic system* (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector connected to a 0.53-mm × 30-m capillary column, coated with a 1.5-µm film of liquid phase G27. The injection port temperature is maintained at about 200°, the detector temperature is maintained at about 280°, and the column temperature is at 120° for 15 minutes then increased at 25° per minute to 250° and maintained for 7 minutes at 250°. Nitrogen is used as the carrier gas at 7.4 mL per minute. Chromatograph the *Standard preparation,* 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 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

*Procedure*—Inject equal volumes (about 1 µL) of the *Assay preparation* and the *Standard preparation* into the gas chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{11}H_{21}N \cdot HCl$ in the portion of Mecamylamine Hydrochloride taken by the formula:

$$50C(R_U/R_S)$$

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

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| Topic/Question | Contact | Expert Committee |
|---|---|---|
| MECAMYLAMINE HYDROCHLORIDE | Documentary Standards Support | SM22020 Small Molecules 2 |

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 28(6)

**Current DocID: GUID-392ED4EF-6989-492D-88C4-EA3E54013465_5_en-US**

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https://trungtamthuoc.com/
**DOI:** https://doi.org/10.31003/USPNF_M47670_05_01
**DOI ref:** 84kpm

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