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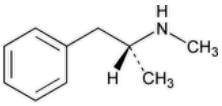
Levmetamfetamine



$C_{10}H_{15}N$ 149.23

Benzeneethanamine, *N*, α-dimethyl-, (*R*)-.

(−)-(*R*)-*N*, α-Dimethylphenethylamine CAS RN®: 33817-09-3; UNII: Y24T9BT2Q2.

» Levmetamfetamine contains not less than 98.0 percent and not more than 100.5 percent of $C_{10}H_{15}N$.

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

USP Reference standards ⟨11⟩—

USP Levmetamfetamine RS

USP Methamphetamine Hydrochloride RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197F*▲ (CN 1-May-2020) ·

B: The retention time of the major peak in the chromatogram of the *Test solution* corresponds to that in the chromatogram of the *System suitability solution*, as obtained in the test for *Limit of methamphetamine*.

Specific rotation ⟨781S⟩: between −18.5° and −21.5°.

Test solution: 16 mg per mL, in 1.2 N hydrochloric acid.

Limit of methamphetamine—

Mobile phase—Prepare a filtered and degassed mixture of hexane, isopropyl alcohol, and acetonitrile (98:1.5:0.5). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Resolution solution—Mix suitable quantities of a solution of USP Methamphetamine Hydrochloride RS in chloroform and USP Levmetamfetamine RS in chloroform to obtain a solution containing about 0.025 mg per mL and 2.5 mg per mL of methamphetamine hydrochloride and levmetamfetamine, respectively. Transfer 2.0 mL of this solution to a suitable container, add 10 mg of 2-naphthyl chloroformate and 2.0 mL of chloroform, mix with a vortex mixer, and allow to stand for 5 minutes. To this solution, add 2 mL of 1 N sodium hydroxide, mix with a vortex mixer, allow to stand for 5 minutes, and discard the aqueous layer. Wash the organic layer twice with 2 mL of 1 N sodium hydroxide, discarding the aqueous layer. To the organic layer add 2 mL of 1 N hydrochloric acid, mix with a vortex mixer, and discard the aqueous layer. Wash the organic layer twice with 2 mL of 1 N hydrochloric acid, discarding the aqueous layer. To the organic layer add 2 mL of water, mix with a vortex mixer, and discard the aqueous layer. Wash the organic layer twice with 2 mL of water, discarding the aqueous layer. To the organic layer add about 1.0 g of anhydrous sodium sulfate, and mix with a vortex mixer. Transfer 1.0 mL of this solution to a 10-mL volumetric flask, dilute with *Mobile phase* to volume, mix, and filter.

Test solution—Transfer about 62.5 mg of Levmetamfetamine, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with chloroform to volume, and mix. Transfer 2.0 mL of this solution to a suitable container, and proceed as directed in *Resolution solution* beginning with "add 10 mg of 2-naphthyl chloroformate and 2 mL of chloroform."

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 274-nm detector and a 4.6-mm × 25-cm column that contains packing L36. The flow rate is about 1.5 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.9 for methamphetamine and 1.0 for levmetamfetamine; and the resolution, *R,* between methamphetamine and levmetamfetamine is not less than 1.4. Chromatograph the *Test solution*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Inject a volume (about 50 µL) of the *Test solution* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the percentage of methamphetamine in the portion of Levmetamfetamine taken by the formula:

$$100r_M/(r_M + r_L)$$

in which r_M is the methamphetamine peak response obtained from the *Test solution*, and r_L is the peak response of levmetamfetamine obtained from the *Test solution:* not more than 0.1% is found.

Limit of nonvolatile residue—Heat about 1.0 g, accurately weighed, at 150° to constant weight: the limit is not more than 0.5%.

Ordinary impurities ⟨466⟩—

Test solution: chloroform.

Standard solution: chloroform.

Eluant: a mixture of chloroform, cyclohexane, and diethylamine (5:4:1).

Visualization: 1.

Limits—No impurity exceeds 0.1%, and the total does not exceed 0.5%.

Assay—Transfer about 400 mg of Levmetamfetamine to a suitable container, add 50.0 mL of glacial acetic acid, and mix. Add two drops of crystal violet TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 14.92 mg of $C_{10}H_{15}N$.

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

Topic/Question	Contact	Expert Committee
LEVMETAMFETAMINE	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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