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Methamphetamine Hydrochloride Tablets

DEFINITION

Methamphetamine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of methamphetamine hydrochloride ($C_{10}H_{15}N \cdot HCl$).

IDENTIFICATION

• **A.** The UV absorption spectrum of the *Sample solution*, prepared as described in *Procedure for content uniformity* in *Uniformity of Dosage Units*, exhibits maxima and minima at the same wavelengths as those of the *Standard solution*, concomitantly measured.

ASSAY

• **Procedure**

Mobile phase: Prepare a degassed solution of 1.1 g of sodium 1-heptanesulfonate in a mixture of water, methanol, and diluted glacial acetic acid (7 in 50) (575:400:25). Adjust with acetic acid to a pH of 3.3 ± 0.1, if necessary. Filter through a 0.5-µm disk.

Standard solution: 0.2 mg/mL of USP Methamphetamine Hydrochloride RS in 0.12 M phosphoric acid. Sonicate if necessary.

Sample solution: Transfer a portion of fine powder from NLT 20 Tablets, nominally equivalent to about 10 mg of methamphetamine hydrochloride, to a 50-mL volumetric flask. Add 20 mL of 0.12 M phosphoric acid, and sonicate for 5 min. Dilute with 0.12 M phosphoric acid to volume, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 257 nm

Column: 3.9-mm × 30.0-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methamphetamine hydrochloride ($C_{10}H_{15}N \cdot HCl$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Methamphetamine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of methamphetamine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: Acetonitrile and dilute perchloric acid (1 in 20) (300:700). Filter, and degas.

Sample solution: Filter aliquots of the solution in the test, and dilute 2:1 with 0.15 M perchloric acid.

Standard solution: Dissolve USP Methamphetamine Hydrochloride RS in water to obtain a concentration similar to the one expected in the *Sample solution*. Dilute 2:1 with 0.15 M perchloric acid.

Chromatographic system

Mode: LC

Detector: UV 211 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2.5 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of the labeled amount of methamphetamine hydrochloride ($C_{10}H_{15}N \cdot HCl$) dissolved by comparing the major peak response of the *Sample solution* with that of the *Standard solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of methamphetamine hydrochloride ($C_{10}H_{15}N \cdot HCl$) is dissolved.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Solution A: Shake 250 mL of 0.1 N sulfuric acid with 25 mL of chloroform for 10 min. Allow to stand for 1 h with occasional shaking. Drain off the chloroform, and retain the chloroform-saturated sulfuric acid in a stoppered flask.

Standard solution: 0.5 mg/mL of USP Methamphetamine Hydrochloride RS in *Solution A*

Sample solution: Place 1 Tablet in a 125-mL separator. Add 15 mL of water, and shake by mechanical means for 15 min to dissolve. Add 2.5 mL of 1 N sodium hydroxide, and shake. Extract the liberated methamphetamine with four 10-mL portions of chloroform, collecting the chloroform extracts in a second 125-mL separator. Transfer 10.0 mL of *Solution A* to the second separator, and shake by mechanical means for 10 min. Allow the layers to separate, and collect the aqueous layer.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum at about 257 nm

Cell: 1 cm

Blank: *Solution A*

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Calculate the percentage of the labeled amount of methamphetamine hydrochloride ($C_{10}H_{15}N \cdot HCl$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Methamphetamine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of methamphetamine hydrochloride in the *Sample solution* (mg/mL)

▲▲ (CN 1-Aug-2023)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Methamphetamine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
METHAMPHETAMINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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