Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-CC7AABC0-3370-4230-94A3-8E09A132C888_2_en-US
DOI: https://doi.org/10.31003/USPNF_M52730_02_01
DOI Ref: 9um49

Methylphenidate Hydrochloride Tablets

DEFINITION

Methylphenidate Hydrochloride Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of methylphenidate hydrochloride ($C_{14}H_{19}NO_2 \cdot HCl$).

IDENTIFICATION

Change to read:

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

Sample: Equivalent to 50 mg of methylphenidate hydrochloride from a portion of powdered Tablets in a 40-mL centrifuge tube. Add 10 mL of chloroform, shake, and centrifuge. Filter the clear extract through a medium-sized sintered-glass funnel into a beaker, and repeat the extraction with an additional 10-mL portion of chloroform. Evaporate the combined chloroform extracts on a steam bath to dryness. Agitate the dried residue with 2 mL of acetonitrile, and filter the mixture through a small sintered-glass funnel. Wash the crystals with an additional 2 mL of acetonitrile, and dry them with the aid of suction.

Acceptance criteria: Meet the requirements

ASSAY

• **Procedure**

Buffer: Dissolve 1.6 g of anhydrous sodium acetate in 900 mL of water. Adjust with acetic acid to a pH of 4.0. Dilute with water to 1 L.

Mobile phase: Methanol, acetonitrile, and *Buffer* (4:3:3)

Internal standard solution: 0.4 mg/mL of phenylephrine hydrochloride in *Mobile phase*

Standard stock solution: 0.2 mg/mL of USP Methylphenidate Hydrochloride RS in *Mobile phase*

Standard solution: Mix 10.0 mL of the *Standard stock solution* with 5.0 mL of the *Internal standard solution*

Sample stock solution: 0.2 mg/mL of methylphenidate hydrochloride from finely powdered Tablets (NLT 20 Tablets) prepared as follows. Dissolve in *Mobile phase* using 70% of the final volume. Sonicate for 15 min, and cool to room temperature. Dilute with *Mobile phase* to volume. Pass a portion of this solution through a suitable membrane filter, discarding the first portion of the filtrate. Avoid the use of glass filters. Polypropylene filters are suitable for use.

Sample solution: Mix 10.0 mL of the clear filtrate from the *Sample stock solution* with 5.0 mL of the *Internal standard solution*.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; packing L10

Flow rate: 1.5 mL/min

Injection size: 50 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for phenylephrine hydrochloride and methylphenidate hydrochloride are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the analyte and the internal standard peaks

Relative standard deviation: NMT 2.0% from the peak response ratios of the analyte to the internal standard

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methylphenidate hydrochloride ($C_{14}H_{19}NO_2 \cdot HCl$) in the portion of Tablets taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of the analyte to the internal standard from the *Sample solution*

R_S = peak response ratio of the analyte to the internal standard from the *Standard solution*

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

C_U = nominal concentration of Methylphenidate Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩**,** *Procedure for a Pooled Sample*

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Analysis: Determine the amount of methylphenidate hydrochloride ($C_{14}H_{19}NO_2 \cdot HCl$) dissolved by using the procedure in the *Assay,* making any necessary volumetric adjustments.

Tolerances: NLT 75% (*Q*) of the labeled amount of $C_{14}H_{19}NO_2 \cdot HCl$ is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Methylphenidate Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
METHYLPHENIDATE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(4)

Current DocID: GUID-CC7AABC0-3370-4230-94A3-8E09A132C888_2_en-US

DOI: https://doi.org/10.31003/USPNF_M52730_02_01

DOI ref: 9um49