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Methadone Hydrochloride Tablets for Oral Suspension

DEFINITION

Methadone Hydrochloride Tablets for Oral Suspension contain NLT 93.0% and NMT 107.0% of the labeled amount of methadone hydrochloride ($C_{21}H_{27}NO \cdot HCl$).

IDENTIFICATION

• A. [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Sample solution: Shake a quantity of powdered Tablets for Oral Suspension equivalent to 5 mg of methadone hydrochloride with 5 mL of sodium carbonate TS, and extract with 5 mL of chloroform.

Developing solvent system: Alcohol, glacial acetic acid, and water (5:3:2)

Analysis: Proceed as directed, using iodoplatinate TS to visualize the spots.

Acceptance criteria: Meet the requirements

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile and 0.03 M monobasic potassium phosphate (40:60). Adjust with phosphoric acid to a pH of 3.2.

Standard solution: 0.4 mg/mL of [USP Methadone Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.4 mg/mL of methadone hydrochloride in *Mobile phase*. Prepare by transferring an amount of finely powdered Tablets for Oral Suspension (NLT 20) equivalent to 10 mg of methadone hydrochloride to a 25-mL volumetric flask, adding 10 mL of *Mobile phase*, and sonicating briefly. Shake by mechanical means for 15 min, dilute with *Mobile phase* to volume, and filter.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L11

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methadone hydrochloride ($C_{21}H_{27}NO \cdot HCl$) in the portion of Tablets for Oral Suspension 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 Methadone Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

- [DISINTEGRATION <701>](#)

Time: 15 min

Acceptance criteria: Meet the requirements

- [UNIFORMITY OF DOSAGE UNITS <905>](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label the Tablets for Oral Suspension to indicate that they are intended for dispersion in a liquid before oral administration of the prescribed dose.
- [USP REFERENCE STANDARDS <11>](#)
[USP Methadone Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
METHADONE HYDROCHLORIDE TABLETS FOR ORAL SUSPENSION	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](#)

Most Recently Appeared In:

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