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Methadone Hydrochloride Oral Concentrate

DEFINITION

Methadone Hydrochloride Oral Concentrate contains, in each mL, NLT 9.0 mg and NMT 11.0 mg of methadone hydrochloride ($C_{21}H_{27}NO \cdot HCl$).

It contains a suitable preservative and may contain suitable coloring, flavoring, and surface-active agents.

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201⟩**

Sample solution: A volume of Oral Concentrate equivalent to 5 mg of methadone hydrochloride

Chromatographic system

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

Analysis: Shake the *Sample solution* with 5 mL of sodium carbonate TS, and extract with 5 mL of chloroform. Proceed as directed, using iodoplatinate TS to visualize the spots.

Acceptance criteria: Meets the requirements

• **B. Identification Tests—General, *Chloride*⟨191⟩:** Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 0.033 M monobasic potassium phosphate (40:60). Adjust with phosphoric acid to a pH of 4.0, filter, and degas.

Standard solution: 0.4 mg/mL of USP Methadone Hydrochloride RS in *Mobile phase*

Sample stock solution: Nominally 1 mg/mL of methadone hydrochloride from Oral Concentrate in *Mobile phase*

Sample solution: 0.4 mg/mL of methadone hydrochloride in *Mobile phase* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L11

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the labeled amount of methadone hydrochloride ($C_{21}H_{27}NO \cdot HCl$) in the portion of Oral Concentrate taken:

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

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 the *Sample solution* (mg/mL)

L = label claim (mg/mL)

Acceptance criteria: 9.0–11.0 mg/mL

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 1.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, protected from light, and store at controlled room temperature.

• **Labeling:** Label it to indicate that it is to be diluted with water or other liquid to 30 mL or more before administration.

• **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 ORAL CONCENTRATE	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

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