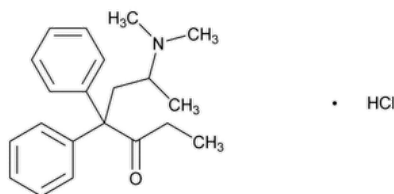


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Methadone Hydrochloride



$C_{21}H_{27}NO \cdot HCl$ 345.91

3-Heptanone, 6-(dimethylamino)-4,4-diphenyl-, hydrochloride;

6-(Dimethylamino)-4,4-diphenyl-3-heptanone hydrochloride CAS RN®: 1095-90-5; UNII: 229809935B.

DEFINITION

Methadone Hydrochloride contains NLT 98.5% and NMT 100.5% of methadone hydrochloride ($C_{21}H_{27}NO \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): A solution meets the requirements of the tests.

ASSAY

PROCEDURE

Sample: 500 mg

Mode: Direct titration

Titrimetric system

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Visual

Analysis: Dissolve the *Sample* in a mixture of 10 mL of glacial acetic acid and 10 mL of mercuric acetate TS, warming slightly if necessary to dissolve. Cool the solution to room temperature, add 10 mL of dioxane, then add crystal violet TS, and titrate rapidly with *Titrant*. Perform a blank determination, and make any necessary correction (see [Titrimetry \(541\)](#)). Each mL of *Titrant* is equivalent to 34.59 mg of methadone hydrochloride ($C_{21}H_{27}NO \cdot HCl$).

Acceptance criteria: 98.5%–100.5% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%
- [ORDINARY IMPURITIES \(466\)](#)

Standard solution: Alcohol

Sample solution: Alcohol

Eluant: Methanol and ammonium hydroxide (100:1.5)

Visualization: 3

Acceptance criteria: The sum of the intensities of all secondary spots from the *Sample solution* corresponds to NMT 1.0%.

SPECIFIC TESTS

- [pH \(791\)](#)

Sample solution: 10 mg/mL

Acceptance criteria: 4.5–6.5

- [LOSS ON DRYING \(731\)](#)

Sample: 500 mg

Analysis: Dry the *Sample* at 105° for 1 h.

Acceptance criteria: NMT 0.3%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.

- [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	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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