Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-6768563C-FEEA-45D0-80A6-8241ACAB613B_4_en-US
DOI: https://doi.org/10.31003/USPNF_M51530_04_01
DOI Ref: n8n0y

Methotrimeprazine Injection

DEFINITION

Methotrimeprazine Injection is a sterile solution of Methotrimeprazine in Water for Injection, prepared with the aid of hydrochloric acid. It contains NLT 90.0% and NMT 110.0% of the labeled amount of methotrimeprazine ($C_{19}H_{24}N_2OS$), as the hydrochloride.

[Note—Throughout the following procedures, protect test or assay specimens, the Reference Standard, and solutions containing them by conducting the procedures without delay under subdued light or by using low-actinic glassware.]

IDENTIFICATION

Change to read:

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

Sample: Place 1 mL of Injection in a 125-mL separator, and add 1 N sodium hydroxide dropwise until the solution becomes opaque white. Extract with 50 mL of ether, wash the ether extract with 25 mL of water, and discard the washing. Filter the ether extract through a layer of anhydrous sodium sulfate into a beaker, and evaporate the filtrate by means of a stream of nitrogen to complete dryness. Dry at 100° for 3 h.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Solution A: Transfer 23.5 mL of 85% phosphoric acid into a 100-mL volumetric flask containing water, and dilute with water to volume.

Mobile phase: Add 20 mL of *Solution A* to 450 mL of water. To this solution add 5 mL of triethylamine, and adjust with 1 N sodium hydroxide to a pH of 3.0. Add 500 mL of acetonitrile, and dilute with water to 1000 mL. Filter, and degas.

System suitability solution: 2.0 mg/mL of benzyl alcohol, using appropriate amounts of 1% benzyl alcohol, and 0.1 mg/mL of USP Methotrimeprazine RS in *Mobile phase*

Standard solution: 0.1 mg/mL of USP Methotrimeprazine RS in *Mobile phase*

Sample solution: Nominally equivalent to 0.1 mg/mL of methotrimeprazine in *Mobile phase* from an appropriate amount of Injection

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 4.0 between benzyl alcohol and methotrimeprazine, *System suitability solution*

Tailing factor: NMT 1.2, *System suitability solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methotrimeprazine ($C_{19}H_{24}N_2OS$) in the portion of Injection 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 Methotrimeprazine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 3.0–5.0
- **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 17.9 USP Endotoxin Units/mg of methotrimeprazine
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.
- **USP Reference Standards** ⟨11⟩
  USP Methotrimeprazine RS

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

Topic/Question	Contact	Expert Committee
METHOTRIMEPRAZINE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 28(6)

Current DocID: GUID-6768563C-FEEA-45D0-80A6-8241ACAB613B_4_en-US

DOI: https://doi.org/10.31003/USPNF_M51530_04_01

DOI ref: n8n0y