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Methocarbamol Injection

DEFINITION

Methocarbamol Injection is a sterile solution of Methocarbamol in an aqueous solution of Polyethylene Glycol 300. It contains NLT 95.0% and NMT 105.0% of the labeled amount of methocarbamol ($C_{11}H_{15}NO_5$).

IDENTIFICATION

Change to read:

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

Sample: Mix a volume with 40 mL of water equivalent to 500 mg of methocarbamol from Injection in a small separator. Extract with 10 mL of ethyl acetate, and dry the ethyl acetate layer over anhydrous sodium sulfate. Evaporate the ethyl acetate with the use of a water bath maintained at 40° under a stream of nitrogen to dryness.

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid or potassium hydroxide to a pH of 4.5.

Mobile phase: Methanol and *Buffer* (30:70)

Standard solution: 1 mg/mL of USP Methocarbamol RS in *Mobile phase*

Sample solution: Nominally 1 mg/mL of methocarbamol from a suitable volume of Injection containing NLT 100 mg of methocarbamol in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 274 nm

Column: 4.6-mm × 10.0-cm; 3-µm or 5-µm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methocarbamol ($C_{11}H_{15}NO_5$) 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 Methocarbamol RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **Limit of Aldehydes**

Diluent: Alcohol and water (20:80)

Solution A: 10 mg/mL of phenylhydrazine hydrochloride in *Diluent*

Solution B: 10 mg/mL of potassium ferricyanide in water

Solution C: 10 µg/mL of formaldehyde in water prepared as follows. Dissolve 1.37 g of formaldehyde solution in 1 L of water. Dilute 10 mL of the resulting solution with water to 500 mL.

Standard solution: Transfer 4 mL of *Solution C* to a 25-mL volumetric flask. Add 2.0 mL of filtered *Solution A*. Allow to stand for 10 min. Add 1 mL of *Solution B*, and allow to stand for 5 min. Add 4 mL of hydrochloric acid, and dilute with alcohol to volume.

Sample solution: Empty the contents of NLT 10 vials of Injection to a suitable container. Transfer 4.0 mL of the composite sample of Injection to a 25-mL volumetric flask. Add 2.0 mL of filtered *Solution A*, and allow to stand for 10 min. Add 1 mL of *Solution B*, and allow to stand for 5 min. Add 4 mL of hydrochloric acid, and dilute with alcohol to volume.

Blank: Transfer 4 mL of water to a 25-mL volumetric flask. Add 2.0 mL of filtered *Solution A*, and allow to stand for 10 min. Add 1 mL of *Solution B*, and allow to stand for 5 min. Add 4 mL of hydrochloric acid, and dilute with alcohol to volume.

Instrumental conditions

Mode: Vis

Analytical wavelength: 515 nm

Cell: 1 cm

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Determine the absorbances of the *Samples*.

Acceptance criteria: The absorbance of the *Sample solution* is NMT the absorbance of the *Standard solution* (NMT 10 µg of formaldehyde in each mL of Injection).

SPECIFIC TESTS

- **pH ⟨791⟩:** 3.5–6.0
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.2 USP Endotoxin Units/mg of methocarbamol
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers. Store at controlled room temperature.
- **USP Reference Standards ⟨11⟩**
  USP Methocarbamol RS

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

Topic/Question	Contact	Expert Committee
METHOCARBAMOL INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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