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Methocarbamol Tablets

DEFINITION
Methocarbamol Tablets contain 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 portion of finely powdered Tablets equivalent to 1 g of methocarbamol with 25 mL of water in a separator, and extract with 25 mL of chloroform. Filter the extract, and evaporate to dryness.

Acceptance criteria: Meet the requirements

• **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 sodium hydroxide to a pH of 4.5.

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

System suitability solution: 1.0 mg/mL of USP Methocarbamol RS and 0.005 mg/mL of USP Guaifenesin RS in *Mobile phase*

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

Sample stock solution: Nominally 1 mg/mL of methocarbamol solution prepared as follows. Transfer a portion of finely powdered Tablets (NLT 10) to a volumetric flask of suitable size. Add 60% of the volume of the flask with *Mobile phase*. Sonicate for 30 min with intermittent shaking. Dilute with *Mobile phase* to volume. Pass a portion of the solution through a suitable filter of 0.45-µm pore size.

Sample solution: Nominally 0.1 mg/mL of methocarbamol from the *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 274 nm

Column: 4.6-mm × 15-cm; 3-µm packing L1

Column temperature: 30°

Flow rate: 0.8 mL/min

Injection volume: 20 µL

Run time: 1.5 times the retention time of methocarbamol

System suitability

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

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 3.5 between methocarbamol and guaifenesin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

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 Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of methocarbamol from the *Sample solution*

r_S = peak response of methocarbamol 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%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard solution: USP Methocarbamol RS in *Medium*

Sample solution: Filtered portion of the solution under test, diluted with *Medium* if necessary

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of methocarbamol ($C_{11}H_{15}NO_5$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

r_U = peak response of methocarbamol from the *Sample solution*

r_S = peak response of methocarbamol from the *Standard solution*

C_S = concentration of USP Methocarbamol RS in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim for methocarbamol (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of methocarbamol ($C_{11}H_{15}NO_5$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

IMPURITIES

• **Organic Impurities**

Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.005 mg/mL of USP Methocarbamol RS in *Mobile phase*

Sample solution: Use the *Sample stock solution* from the *Assay*.

System suitability

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

[Note—See *Table 1* for relative retention times.]

Suitability requirements

Resolution: NLT 3.5 between methocarbamol and guaifenesin, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each degradation product from the *Sample solution*

r_S = peak response of methocarbamol 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)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Guaifenesin	0.84	1.2	0.15
Methocarbamol isomer[a]	0.90	1.0	0.05

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Methocarbamol	1.0	—	—
Methocarbamol dioxolone[b]	1.3	1.0	0.05
Any individual unspecified degradation product	—	—	0.10
Total impurities	—	—	1.0

[a] 1-Hydroxy-3-(2-methoxyphenoxy)propan-2-yl carbamate.

[b] 4-[(2-Methoxyphenoxy)methyl]-1,3-dioxolan-2-one.

ADDITIONAL REQUIREMENTS

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

USP Guaifenesin RS
USP Methocarbamol RS

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

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

Chromatographic Database Information: Chromatographic Database

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