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.▲*USP38*INFRARED ABSORPTION ⟨197K⟩**
  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

Add the following:

▲• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲*USP38*

ASSAY

Change to read:

- **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: 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)▲*USP38*

Acceptance criteria: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

- **DISSOLUTION ⟨711⟩**
  ▲▲*USP38*
  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▲*USP38*
  Analysis
  ▲Samples: *Standard solution* and *Sample solution*▲*USP38*
  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 of methocarbamol (mg/Tablet)

▲*USP38*

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

Change to read:

▲• 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 factors (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
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.

•(Postponed Indefinitely)• (RB 1-May-2015)

▲*USP38*

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in tight containers. ▲Store at controlled room temperature.▲*USP38*

Change to read:

- **USP REFERENCE STANDARDS** ⟨**11**⟩
  ▲USP Guaifenesin RS▲*USP38*
  USP Methocarbamol RS