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Carisoprodol Tablets

DEFINITION
Carisoprodol Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of carisoprodol ($C_{12}H_{24}N_2O_4$).

IDENTIFICATION

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

Change to read:

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

Standard: Use a suitable portion of USP Carisoprodol RS.

Sample: Powder a Tablet and use a suitable portion to prepare a specimen.

Analysis

Samples: *Standard* and *Sample*

Compare the background corrected spectra in the range between 4000 and 400 cm^{-1}.

Acceptance criteria: The spectrum obtained from the *Sample* shows bands at approximately 3445, 1689, 1604, 1525, 1410, 1244, 1072, and 780 cm^{-1}, similar to the spectrum from the *Standard*. [Note—Peak positions may vary slightly between instruments (±10 cm^{-1}). Other peaks may be present in the spectra that do not appear on the list.]

ASSAY

• **Procedure**

Diluent: Acetonitrile and water (50:50)

Mobile phase: Acetonitrile and water (25:75)

System suitability solution: 0.1 mg/mL each of USP Carisoprodol Related Compound A RS, USP Meprobamate RS, and USP Carisoprodol RS in *Diluent*

Standard solution: 2.5 mg/mL of USP Carisoprodol RS in *Diluent*

Sample solution: Nominally 2.5 mg/mL of carisoprodol in *Diluent* prepared as follows. Transfer a quantity equivalent to the label claim of carisoprodol from powdered Tablets (NLT 20) to a suitable volumetric flask, and fill 50% of the flask volume with *Diluent*. Place in an ultrasonic bath for 30 min, and shake mechanically for 60 min. Dilute with *Diluent* to volume. Pass a portion of this solution through a suitable membrane filter, and use the filtrate as the *Sample solution*.

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 15-cm; 4-µm packing L1

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 25 µL

Run time: 1.5 times the retention time of carisoprodol

System suitability

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

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

Suitability requirements

Resolution: NLT 1.5 between carisoprodol related compound A and meprobamate, *System suitability solution*

Tailing factor: NMT 2.5 for the carisoprodol peak, *Standard solution*

Relative standard deviation: NMT 2.0% for the carisoprodol peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carisoprodol ($C_{12}H_{24}N_2O_4$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.05 M phosphate buffer, pH 6.9 (see *Reagents, Indicators, and Solutions—Buffer Solutions*) containing 5 units of α-amylase per mL; 900 mL

[Note—Use only freshly prepared solutions containing α-amylase; and equilibrate the *Medium* at 37° for NMT 1 h before beginning the *Dissolution* test.]

Apparatus 2: 75 rpm

Time: 60 min

Mobile phase: Acetonitrile and water (40:60)

System suitability solution: 2.4 mg/mL of 2-methyl-2-propyl-1,3-propanediol and 3.4 mg/mL of USP Carisoprodol RS in *Mobile phase*

Standard solution: 0.4 mg/mL of USP Carisoprodol RS in *Medium*

[Note—A volume of acetonitrile not exceeding 2% of the final volume of solution may be used to aid in dissolving carisoprodol.]

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: Refractive index

Column: 3.9-mm × 30-cm; packing L1

Temperatures

Column: 30 ± 1°

Detector: 30 ± 1°

Flow rate: 2 mL/min

Injection volume: 150 µL

System suitability

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

[Note—The relative retention times for 2-methyl-2-propyl-1,3-propanediol and carisoprodol are about 0.5 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between 2-methyl-2-propyl-1,3-propanediol and carisoprodol, *System suitability solution*

Relative standard deviation: NMT 2.0% for three replicate injections of the *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Record the peak responses, and measure the heights for the major peaks.

Calculate the percentage of the labeled amount of carisoprodol ($C_{12}H_{24}N_2O_4$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 80% (*Q*) of the labeled amount of carisoprodol ($C_{12}H_{24}N_2O_4$) is dissolved.

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

IMPURITIES

• **Organic Impurities**

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

Standard solution: 0.01 mg/mL of USP Carisoprodol RS in *Diluent*

Sample solution: Nominally 10 mg/mL of carisoprodol in *Diluent* prepared as follows. Transfer a quantity equivalent to four times the label claim of carisoprodol from powdered Tablets (NLT 20 Tablets) to a suitable volumetric flask, and fill 50% of the flask volume with *Diluent*. Place in an ultrasonic bath for 30 min, and shake mechanically for 60 min. Dilute with *Diluent* to volume. Pass a portion of this solution through a suitable membrane filter, and use the filtrate as the *Sample solution*.

System suitability

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

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

Suitability requirements

Resolution: NLT 1.5 between carisoprodol related compound A and meprobamate, *System suitability solution*

Tailing factor: NMT 2.5 for the carisoprodol peak, *Standard solution*

Relative standard deviation: NMT 5.0% for the carisoprodol peak for three replicate injections of the *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the specified impurities using the relative retention times given in *Table 1*.

Calculate the percentage of each impurity 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 impurity from the *Sample solution*

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

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

C_U = nominal concentration of carisoprodol 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 (%)
Carisoprodol related compound A	0.19	0.06	0.75
Meprobamate	0.24	0.08	0.65
Carisoprodol monocarbamate[a]	0.86	1.4	0.20
Carisoprodol	1.0	—	—
Any other unknown degradation product	—	1.0	0.20
Total impurities	—	—	1.25

[a] 2-Hydroxymethyl-2-methylpentyl isopropylcarbamate.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers at controlled room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Carisoprodol RS

USP Carisoprodol Related Compound A RS

2-Hydroxymethyl-2-methylpentyl carbamate.

$C_8H_{17}NO_3$ 175.23

USP Meprobamate RS

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

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

Chromatographic Database Information: Chromatographic Database

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