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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 ($\pm 10\text{ }cm^{-1}$). 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 $\times$ 15-cm; 4- μ m packing [L1](#)

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 25 μ L

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*.