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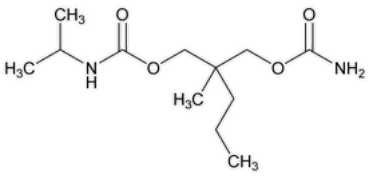
Carisoprodol



$C_{12}H_{24}N_2O_4$ 260.33

(±)-2-Methyl-2-propyl-1,3-propanediol carbamate isopropylcarbamate CAS RN®: 78-44-4; UNII: 21925K482H.

DEFINITION

Carisoprodol contains NLT 98.0% and NMT 102.0% of $C_{12}H_{24}N_2O_4$, calculated on the dried basis.

IDENTIFICATION

Change to read:

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

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

ASSAY

• **Procedure**

Diluent: Acetonitrile and water (50:50)

Solution A: Acetonitrile and water (25:75)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
35	100	0
36	80	20
51	80	20
52	100	0
60	100	0

System suitability solution: 0.125 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: 2.5 mg/mL of Carisoprodol in *Diluent*

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 size: 25 µL

System suitability

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

[Note—See *Table 2* 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 carisoprodol ($C_{12}H_{24}N_2O_4$) in the portion of the sample 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 = concentration of Carisoprodol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Change to read:

• **Organic Impurities**

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

Standard solution: 10 µg/mL of USP Carisoprodol RS in *Diluent*

Sample solution: 50 mg/mL of Carisoprodol in *Diluent*. [Note—Sonication may be used to aid dissolution.]

System suitability

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

[Note—See *Table 2* 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, 3 replicate injections of *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the specified impurities using the relative retention times given in *Table 2*.

Calculate the percentage of each impurity in the portion of Carisoprodol taken:

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

r_U = peak response of the 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 = concentration of Carisoprodol in the *Sample solution* (mg/mL)

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
▲Carisoprodol▲ (ERR 1-May-2020) related compound A[a]	0.19	0.06	0.1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Meprobamate	0.24	0.08	0.5
Carisoprodol monocarbamate[b]	0.86	1.4	0.1
Carisoprodol	1.0	—	—
Any other unknown individual impurity	—	1.0	0.1
Total impurities	—	—	1.0

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

[b] *N*-Isopropyl-2-hydroxymethyl-2-methylpentyl carbamate.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩:** Dry a sample in vacuum at 60° for 3 h: it loses NMT 0.5% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers at 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	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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