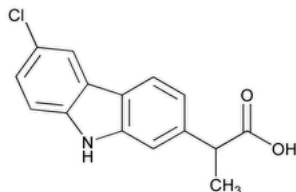


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Carprofen



$C_{15}H_{12}ClNO_2$ 273.71

9H-Carbazole-2-acetic acid, 6-chloro-α-methyl-, (±)-;

(±)-6-Chloro-α-methylcarbazole-2-acetic acid CAS RN®: 53716-49-7; UNII: FFL0D546HO.

DEFINITION

Carprofen contains NLT 98.0% and NMT 102.0% of carprofen ($C_{15}H_{12}ClNO_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020) : [NOTE—Methods described in [\(197K\)](#) or [\(197A\)](#), may be used. If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in [acetone](#), evaporate to dryness, and record new spectra using the residues.]
- **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

[NOTE—Protect all solutions containing carprofen from light.]

Mobile phase: [Acetonitrile](#), [methanol](#), [glacial acetic acid](#), and [water](#) (40:25:0.2:35)

System suitability stock solution: 16 µg/mL of [USP Carprofen Related Compound A RS](#) in *Mobile phase*. Sonicate if necessary.

Standard solution: 160 µg/mL of [USP Carprofen RS](#) in *Mobile phase*. Sonicate if necessary.

System suitability solution: 1.6 µg/mL of [USP Carprofen Related Compound A RS](#) and 16 µg/mL of [USP Carprofen RS](#) in *Mobile phase* prepared as follows. Mix 10 mL of *System suitability stock solution* and 10 mL of the *Standard solution* and dilute with *Mobile phase* to 100 mL.

Sample solution: 160 µg/mL of Carprofen in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 239 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 2.0 between carprofen and carprofen related compound A

Tailing factor: NMT 2.0 for the carprofen peak

Relative standard deviation: NMT 2.0% for the carprofen peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carprofen ($C_{15}H_{12}ClNO_2$) in the portion of Carprofen taken:

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

r_U = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of [USP Carprofen RS](#) in the *Standard solution* (µg/mL)

C_u = concentration of Carprofen in the *Sample solution* (µg/mL)

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

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

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

Analysis

Sample: *Sample solution*

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

$$\text{Result} = (r_u/r_T) \times 100$$

r_u = peak response of each individual peak (other than the major peak of carprofen)

r_T = sum of all the peak responses

Acceptance criteria: See [Table 1](#).

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Carprofen related compound A (carbazole)	0.9	0.5
2-[1,1-Dimethoxy-2-hydroxypropyl]-6-chlorocarbazole	1.3	0.5
2-[2-Chloropropionyl]-6-chloro-9-acetylcabazole	3.3	0.5
Any individual unspecified impurity	—	0.1
Total impurities	—	1.0

SPECIFIC TESTS

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. Store at 25°, excursions permitted between 15° and 30°.
- **LABELING:** Label it to indicate that it is intended for veterinary use only.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Carprofen RS](#)

[USP Carprofen Related Compound A RS](#)

Carbazole.

$C_{12}H_9N$ 167.21

Topic/Question	Contact	Expert Committee
CARPROFEN	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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