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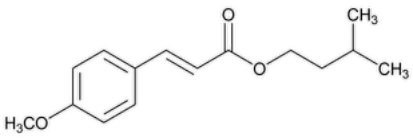
Amiloxate



$C_{15}H_{20}O_3$ 248.32

4-Methoxycinnamic acid, isoamyl ester;

3-Methylbutyl 3-(4-methoxyphenyl)-(*E*)-2-propenoate CAS RN®: 71617-10-2; UNII: 376KTP06K8.

DEFINITION

Amiloxate contains NLT 98.0% and NMT 102.0% of amiloxate ($C_{15}H_{20}O_3$).

IDENTIFICATION

Change to read:

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

Change to read:

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

Sample solution: 5.0 µg/mL in alcohol

• **C.** 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**

Standard solution: 20 mg/mL of USP Amiloxate RS in *tert*-butyl methyl ether

Sample solution: 20 mg/mL of Amiloxate in *tert*-butyl methyl ether

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 25-m; coated with a 0.1-µm film of phase G1

Temperatures

Injection port: 240°

Detector: 260°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	8	240	10

Carrier gas: Helium

Flow rate: 6 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of amiloxate ($C_{15}H_{20}O_3$) in the portion of Amiloxate 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 Amiloxate RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

• **Organic Impurities**

Standard 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 Amiloxate taken:

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

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of all the peak responses, excluding the solvent peak, from the *Sample solution*

Acceptance criteria

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 1.037–1.041

• **Refractive Index ⟨831⟩:** 1.556–1.560 at 20°

• **Acidity**

Sample solution: Transfer 50 mL of alcohol to a suitable container. Add 1 mL of phenolphthalein TS and sufficient 0.1 N sodium hydroxide to obtain a persistent pink color. Transfer 50 mL of this solution to a suitable container, and add 5.0 mL of Amiloxate.

Analysis: Titrate with 0.1 N sodium hydroxide VS.

Acceptance criteria: NMT 0.2 mL of titrant per mL of Amiloxate is required for neutralization.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Amiloxate RS

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

Topic/Question	Contact	Expert Committee
AMILOXATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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