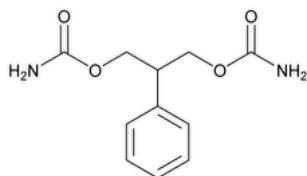


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Felbamate



$C_{11}H_{14}N_2O_4$ 238.24

1,3-Propanediol, 2-phenyl-, dicarbamate;

2-Phenyl-1,3-propanediol dicarbamate CAS RN®: 25451-15-4; UNII: X72RBB02N8.

DEFINITION

Felbamate contains NLT 98.0% and NMT 102.0% of felbamate ($C_{11}H_{14}N_2O_4$), 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 of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: Acetonitrile, methanol, and water (126:84:790)

Diluent: Acetonitrile, methanol, and water (222:148:630)

System suitability solution: 0.05 mg/mL of [USP Felbamate Related Compound A RS](#) and 0.2 mg/mL of [USP Felbamate RS](#) in *Mobile phase*

Standard stock solution: 1.0 mg/mL of [USP Felbamate RS](#) prepared as follows. Dissolve a suitable quantity of [USP Felbamate RS](#) in 10% of the volumetric flask volume of methanol. Sonicate and shake to completely dissolve, and dilute with *Diluent*.

Standard solution: 0.2 mg/mL of [USP Felbamate RS](#) from *Standard stock solution* in *Mobile phase*

Sample stock solution: 1.0 mg/mL of Felbamate prepared as follows. Dissolve a suitable quantity of Felbamate in 10% of the volumetric flask volume of methanol. Sonicate and shake to completely dissolve, and dilute with *Diluent*.

Sample solution: 0.2 mg/mL of Felbamate from *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-μm packing L1

Column temperature: 30°

Flow rate: 1.8 mL/min

Injection volume: 20 μL

Run time: 3 times the retention time of felbamate

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between felbamate related compound A and felbamate, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of felbamate ($C_{11}H_{14}N_2O_4$) in the portion of Felbamate taken:

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

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

r_s = peak response of felbamate from the *Standard solution*

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

C_u = concentration of Felbamate in the *Sample solution* (mg/mL)

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

IMPURITIES

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

• **LIMIT OF METHYLCARBAMATE**

Mobile phase: Water

Standard solution: 0.1 mg/mL of methylcarbamate in water

Sample solution: Suspend 1 g of Felbamate in 5 mL of water, and mix on a vortex mixer for 1 min followed by sonication for 5 min. Filter the slurry, and use as the *Sample solution*.

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 50 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 10%

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The peak response for methylcarbamate in the *Sample solution* does not exceed the peak response for methylcarbamate in the *Standard solution* (0.05%).

• **EARLY ELUTING ORGANIC IMPURITIES**

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

Standard solution: 1 μg/mL of [USP Felbamate RS](#) in *Mobile phase* from *Standard stock solution*

Sample solution: 1.0 mg/mL of Felbamate prepared as follows. Dissolve a suitable quantity of Felbamate in 10% of the volumetric flask volume of methanol. Sonicate and shake to completely dissolve, and dilute with *Diluent*.

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between felbamate related compound A and felbamate, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 10%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Identify the impurities using the relative retention times shown in [Table 1](#).

Calculate the percentage of each impurity in the portion of Felbamate 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 felbamate from the *Standard solution*

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

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

F = relative response factor (see [Table 1](#))

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

Table 1