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Felbamate Tablets

DEFINITION
Felbamate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of felbamate ($C_{11}H_{14}N_2O_4$).

IDENTIFICATION

Change to read:

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

Sample: Transfer a weighed quantity of finely powdered Tablets, equivalent to 12 mg of felbamate, to a centrifuge tube. Add 10 mL of methanol, and mix on a vortex mixer for 3 min. Centrifuge, and transfer 1 mL of the clear supernatant to a mortar with 200 mg of potassium bromide. Evaporate at 105° in an oven for 15 min. Cool the dried residue in a desiccator, and blend by grinding. Prepare a pellet with 100 mg of the dried residue.

Standard: Transfer 1 mL of 1.2 mg/mL of USP Felbamate RS in methanol to a mortar with 200 mg of potassium bromide. Evaporate at 105° in an oven for 15 min. Cool the dried residue in a desiccator, and blend by grinding. Prepare a pellet with 100 mg of the dried residue.

• **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**

Diluent: Methanol and water (80:20)

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

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: 2 mg/mL of USP Felbamate RS in *Diluent*

Standard solution: 0.2 mg/mL of USP Felbamate RS from *Standard stock solution* in *Mobile phase*

Sample stock solution: Nominally 2 mg/mL of felbamate from NLT 20 finely powdered Tablets, prepared as follows. Transfer a weighed quantity of the powder to a suitable volumetric flask. Add 50% of the flask volume of the *Diluent*. Sonicate for 30 min with intermittent shaking. Shake the flask vigorously for NLT 30 min. Dilute with *Diluent* to volume. Pass a portion through a suitable membrane filter.

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 size: 20 µL

Run time: 3 times the retention time of felbamate

System suitability

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

Suitability requirements

Resolution: NLT 2 between felbamate related compound A and felbamate, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of felbamate ($C_{11}H_{14}N_2O_4$) in the portion of the Tablets 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 = nominal concentration of felbamate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Mobile phase: Prepare as directed in the *Assay*.

Standard solution: (*L*/1000) mg/mL of USP Felbamate RS, where *L* is the Tablet label claim, in mg. Transfer a suitable weighed quantity of USP Felbamate RS to a suitable volumetric flask. Add 10% of the flask volume of methanol, and sonicate for 5 min to dissolve. Dilute with *Medium* to volume.

Sample solution: Pass a portion of the solution under test through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.0-mm × 15-cm; 5-µm packing L1

Flow rate: 2 mL/min

Injection size: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of felbamate ($C_{11}H_{14}N_2O_4$) 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 Felbamate RS in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

Tolerances: NLT 65% (*Q*) of the labeled amount of felbamate ($C_{11}H_{14}N_2O_4$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

IMPURITIES

• **Organic Impurities**

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

System suitability stock solution: 0.4 mg/mL of USP Felbamate Related Compound A RS and 0.6 mg/mL of USP Felbamate RS in *Diluent*

System suitability solution: 0.4 µg/mL of USP Felbamate Related Compound A RS and 0.6 µg/mL of USP Felbamate RS from *System suitability stock solution* in *Mobile phase*

Standard stock solution: 0.6 mg/mL of USP Felbamate RS in *Diluent*

Standard solution: 0.6 µg/mL of USP Felbamate RS from *Standard stock solution* in *Mobile phase*

System suitability

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

Suitability requirements

Resolution: NLT 2 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 Tablets 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 *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 = nominal concentration of felbamate in the *Sample solution* (µg/mL)

F = relative response factor (see *Table 1*)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Phenylpropanediol[a]	0.43	1.7	0.2
Felbamate related compound A[b]	0.65	1.3	0.2
Felbamate	1.0	—	—
N-Aminocarbonyl felbamate[c]	1.43	—	—
Felbamate related compound B[d]	2.23	—	—
Individual unspecified degradation product	—	1.0	0.2
Total impurities	—	—	0.75

[a] 2-Phenylpropane-1,3-diol.

[b] 3-Hydroxy-2-phenylpropyl carbamate.

[c] 3-Carbamoyloxy-2-phenylpropyl allophanate.

[d] Phenylethyl carbamate. No limit. This is a process impurity.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.
- **USP Reference Standards** ⟨11⟩

USP Felbamate RS

USP Felbamate Related Compound A RS

3-Hydroxy-2-phenylpropyl carbamate.

$C_{10}H_{13}NO_3$ 195.22

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

Topic/Question	Contact	Expert Committee
FELBAMATE TABLETS	Documentary Standards Support	SM42020 Small Molecules 4

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