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Felbamate Oral Suspension

DEFINITION

Felbamate Oral Suspension is a viscous liquid containing NLT 90.0% and NMT 110.0% of the labeled amount of felbamate ($C_{11}H_{14}N_2O_4$). The product may contain suitable preservatives.

IDENTIFICATION

Change to read:

• **A.** The retention time of the major peak ▲ of ▲ (USP 1-Dec-2020) the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Add the following:

▲ • **B.** The UV spectrum of the felbamate peak in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲
(USP 1-Dec-2020)

ASSAY

Change to read:

• PROCEDURE

Buffer: 28.5 g/L of [tribasic sodium phosphate](#) ▲ (USP 1-Dec-2020) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer* (23:77). Adjust with [phosphoric acid](#) to a pH of 9.9.

Diluent A: [Methanol](#) and water ▲ (50:50) ▲ (USP 1-Dec-2020)

Diluent B: [Acetonitrile](#) and [water](#) (23:77)

System suitability solution: ▲160 µg/mL ▲ (USP 1-Dec-2020) of [USP Felbamate RS](#) and ▲20 µg/mL ▲ (USP 1-Dec-2020) of [USP Felbamate Related Compound A RS](#) in *Diluent B* and [methanol](#) prepared as follows. ▲ Transfer suitable amounts of [USP Felbamate RS](#) and [USP Felbamate Related Compound A RS](#) to an appropriate volumetric flask. Dissolve in 8% of the flask volume of [methanol](#). ▲ (USP 1-Dec-2020) Dilute with *Diluent B* to volume.

Standard solution: ▲160 µg/mL ▲ (USP 1-Dec-2020) of [USP Felbamate RS](#) prepared as follows. ▲ Transfer a suitable amount of [USP Felbamate RS](#) to ▲ (USP 1-Dec-2020) a suitable volumetric flask containing 16% of the flask volume of *Diluent A*. Add 50% of the flask volume of *Diluent B*. Sonication may be used to aid dissolution. Dilute with *Diluent B* to volume.

Sample stock solution: Nominally 1 mg/mL of felbamate in *Diluent A* prepared as follows. Transfer an amount of the Oral Suspension to a suitable volumetric flask. Add 60% of the flask volume of *Diluent A*, and sonicate for 15 min. Shake mechanically for 30 min, and dilute with *Diluent A* to volume.

Sample solution: Nominally ▲160 µg/mL ▲ (USP 1-Dec-2020) of felbamate from *Sample stock solution* in *Diluent B*. Pass through a filter ▲ with a pore size of 0.45-µm. ▲ (USP 1-Dec-2020)

Chromatographic system

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

Mode: LC

Detector: UV 210 nm. ▲ For *Identification B*, use a diode array detector in the range of 190–400 nm. ▲ (USP 1-Dec-2020)

Column: 4.1-mm × 15-cm; 5-µm packing [L21](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection ▲ volume: ▲ (USP 1-Dec-2020) 20 µL

▲ **Run time:** NLT 2 times the retention time of felbamate ▲ (USP 1-Dec-2020)

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 ▲1.5. ▲ (USP 1-Dec-2020) *Standard solution*

Relative standard deviation: NMT $\blacktriangle$ 1.0%, $\blacktriangle$ (USP 1-Dec-2020) *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 Oral Suspension 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* $\blacktriangle$ ($\mu\text{g/mL}$) $\blacktriangle$ (USP 1-Dec-2020)

C_U = nominal concentration of felbamate in the *Sample solution* $\blacktriangle$ ($\mu\text{g/mL}$) $\blacktriangle$ (USP 1-Dec-2020)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 15 min

Mobile phase: [Acetonitrile](#) and [water](#) (35:65)

$\blacktriangle$ **System suitability stock solution:** 0.1 mg/mL of [USP Methylparaben RS](#) in [methanol](#)

System suitability solution: 0.1 mg/mL of [USP Methylparaben RS](#) from *System suitability stock solution* and 0.4 mg/mL of [USP Felbamate RS](#) prepared as follows. Transfer 40 mg of [USP Felbamate RS](#) to a 100-mL volumetric flask. Add 10 mL of *System suitability stock solution* and sonicate for 5 min. Dilute with *Medium* to volume. $\blacktriangle$ (USP 1-Dec-2020)

Standard solution: ($L/1000$) mg/mL of [USP Felbamate RS](#) in *Medium*, where L is the $\blacktriangle$ (USP 1-Dec-2020) label claim in mg/mL. An amount of [methanol](#), not exceeding 10% of the final volume, can be used to help in solubilizing felbamate.

Sample solution: Using a syringe, accurately weigh by difference approximately 5 mL of the well-mixed Oral Suspension. Introduce the sample into the dissolution vessel with the paddles rotating, and avoid getting the sample on the paddle or shaft. At the time specified, withdraw an aliquot of the solution under test, and pass through a suitable filter.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm $\times$ 25-cm; 10- μm packing [L7](#)

Flow rate: 2 mL/min

Injection $\blacktriangle$ volume

System suitability: 25 μL

Analysis: 15 μL

Run time: NLT 3.5 times the retention time of felbamate $\blacktriangle$ (USP 1-Dec-2020)

System suitability

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

[NOTE—The relative retention times for felbamate and methylparaben are about 1.0 and 1.5, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methylparaben and felbamate, *System suitability solution*

Tailing factor: NMT 2, *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 ($C_{11}H_{14}N_2O_4$) dissolved:

$$\blacktriangle \text{Result} = (r_U/r_S) \times C_S \times V \times (d/W) \times (1/L) \times 100 \blacktriangle \text{ (USP 1-Dec-2020)}$$

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)