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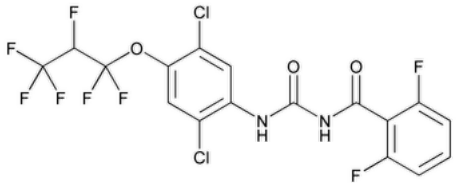
Lufenuron



$C_{17}H_8Cl_2F_8N_2O_3$ 511.15

Benzamide, *N*-[[[2,5-dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy)phenyl]amino]carbonyl]-2,6-difluoro-;

1-[2,5-Dichloro-4-(1,1,2,3,3,3-hexafluoropropoxy)phenyl]-3-(2,6-difluorobenzoyl)urea CAS RN®: 103055-07-8; UNII: 1R754M4918.

DEFINITION

Lufenuron contains NLT 98.0% and NMT 102.0% of lufenuron ($C_{17}H_8Cl_2F_8N_2O_3$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Solution A: 0.1 mL of phosphoric acid diluted with water to 1 L

Solution B: Acetonitrile

Mobile phase: See *Table 1*. Return to original conditions, and equilibrate the system.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	30	70
5	30	70
15	10	90
17	10	90

Diluent: Acetonitrile and water (70:30)

System suitability solution: 0.4 mg/mL of USP Lufenuron RS and 0.14 mg/mL of USP Lufenuron Related Compound G RS in *Diluent*. Sonicate if necessary to facilitate dissolution.

Standard stock solution: 0.4 mg/mL of USP Lufenuron RS in *Diluent*. Sonicate if necessary to facilitate dissolution.

Standard solution: 0.04 mg/mL of USP Lufenuron RS in *Diluent* from *Standard stock solution*

Sample stock solution: 0.4 mg/mL of Lufenuron in *Diluent*. Sonicate if necessary to facilitate dissolution.

Sample solution: 0.04 mg/mL of Lufenuron in *Diluent* from *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 255 nm

Column: 4-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for lufenuron related compound G and lufenuron are 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between lufenuron related compound G and lufenuron, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of lufenuron ($C_{17}H_8Cl_2F_8N_2O_3$) in the portion of Lufenuron 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 Lufenuron RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%
- **ORGANIC IMPURITIES**

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

Identification solution: 1.2 µg/mL of USP Lufenuron Related Compound B RS and 1.6 µg/mL of USP Lufenuron Related Compound C RS in *Diluent*

Diluted standard solution: 0.4 µg/mL of USP Lufenuron RS in *Diluent* from *Standard solution*

Sample solution: 0.4 mg/mL of Lufenuron in *Diluent*. Sonicate if necessary to facilitate dissolution.

Analysis

Samples: *Identification solution*, *Diluted standard solution*, and *Sample solution*

Chromatograph the *Identification solution*, and identify the components on the basis of their relative retention times, given in *Table 2*.

Calculate the percentage of each impurity in the portion of Lufenuron 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 lufenuron from the *Diluted standard solution*

C_S = concentration of USP Lufenuron RS in the *Diluted standard solution* (µg/mL)

C_U = concentration of Lufenuron in the *Sample solution* (µg/mL)

F = relative response factor (see *Table 2*)

Acceptance criteria: See *Table 2*. The reporting level for impurities is 0.1%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Lufenuron related compound B	0.3	0.77	0.3
Lufenuron related compound C	0.7	0.77	0.4
Lufenuron	1.0	—	—

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Any other individual impurity	—	1.0	0.20
Total impurities	—	—	1.0

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° to constant weight.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.

• **Labeling:** Label it to indicate that it is for veterinary use only.

• **USP Reference Standards** ⟨11⟩

USP Lufenuron RS

USP Lufenuron Related Compound B RS

N-[(2,5-Dichloro-4-hydroxyphenyl)carbamoyl]-2,6-difluorobenzamide.

$C_{14}H_8Cl_2F_2N_2O_3$ 361.13

USP Lufenuron Related Compound C RS

N-[3-Chloro-4-(1,1,2,3,3,3-hexafluoropropoxy)phenylcarbamoyl]-2,6-difluorobenzamide.

$C_{17}H_9ClF_8N_2O_3$ 476.71

USP Lufenuron Related Compound G RS

2,5-Dichloro-4-[3-(2,6-difluorobenzoyl)ureido]phenyl phenyl carbonate.

$C_{21}H_{12}Cl_2F_2N_2O_5$ 481.23

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

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

Chromatographic Database Information: Chromatographic Database

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