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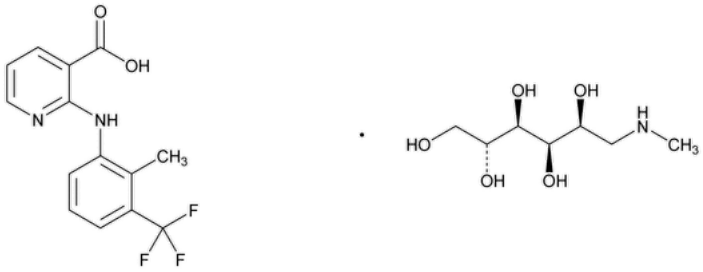
Flunixin Meglumine



$C_{14}H_{11}F_3N_2O_2 \cdot C_7H_{17}NO_5$ 491.46

3-Pyridinecarboxylic acid, 2-[[2-methyl-3-(trifluoromethyl)phenyl]amino]-, compd. with 1-deoxy-1-(methylamino)-D-glucitol (1:1);

2-(α^3,α^3,α^3-Trifluoro-2,3-xylidino)nicotinic acid compound with 1-deoxy-1-(methylamino)-D-glucitol (1:1)

1-Deoxy-1-(methylamino)-D-glucitol 2-{[2-methyl-3-(trifluoromethyl)phenyl]amino}nicotinate CAS RN®: 42461-84-7; UNII: 8Y3JK0JW3U.

DEFINITION

Flunixin Meglumine contains NLT 98.0% and NMT 102.0% of flunixin meglumine ($C_{14}H_{11}F_3N_2O_2 \cdot C_7H_{17}NO_5$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197M**▲ (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 and water (70:30). Add 0.25 mL of phosphoric acid for each L prepared.

System suitability solution: 0.1 mg/mL each of USP Flunixin Meglumine RS and USP Flunixin Related Compound B RS in *Mobile phase*

Standard solution: 0.3 mg/mL of USP Flunixin Meglumine RS in *Mobile phase*

Sample solution: 0.3 mg/mL of Flunixin Meglumine in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 3.0 between flunixin related compound B and flunixin meglumine, *System suitability solution*

Relative standard deviation: NMT 0.73, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of flunixin meglumine ($C_{14}H_{11}F_3N_2O_2 \cdot C_7H_{17}NO_5$) in the portion of Flunixin Meglumine 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 Flunixin Meglumine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0%

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**

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

Standard solution: 0.01 mg/mL each of USP Flunixin Meglumine RS, USP Flunixin Related Compound A RS, USP Flunixin Related Compound B RS, and USP Flunixin Related Compound C RS in *Mobile phase*

Sample solution: 5.0 mg/mL of Flunixin Meglumine in *Mobile phase*

System suitability

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

Suitability requirements

Resolution: NLT 3.0 between flunixin related compound B and flunixin meglumine, *System suitability solution*

Relative standard deviation: NMT 1.0, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of flunixin related compounds A, B, and C in the portion of Flunixin Meglumine taken:

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

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

r_S = peak response of the corresponding related compound from the *Standard solution*

C_S = concentration of the corresponding related compound in the *Standard solution* (mg/mL)

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

Calculate the percentage of flunixin ethyl ester and any other individual impurity in the portion of Flunixin Meglumine taken:

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

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

r_S = peak response of flunixin from the *Standard solution*

C_S = concentration of USP Flunixin Meglumine RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 1*. The reporting level for impurities is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria NMT (%)
Flunixin related compound A[a]	0.5	0.2
Flunixin related compound C[b]	0.7	0.2
Flunixin related compound B[c]	0.8	0.2
Flunixin	1.0	—
Flunixin ethyl ester[d]	4.3	0.2
Any other individual impurity	—	0.2
Total impurities	—	0.5

[a] Chloronicotinic acid; 2-Chloronicotinic acid.

[b] Ethyl chloronicotinate; Ethyl 2-chloronicotinate.

[c] Trifluoromethyl toluidine; 2-Methyl-3-(trifluoromethyl)aniline.

[d] Ethyl 2-{[2-methyl-3-(trifluoromethyl)phenyl]amino}nicotinate.

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample solution: 50 mg/mL in water

  Acceptance criteria: 7.0–9.0

- **Loss on Drying** ⟨731⟩

  Analysis: Dry at 105° for 4 h.

  Acceptance criteria: NMT 0.5%

- **Optical Rotation,** *Specific Rotation*⟨781S⟩

  Sample solution: 120 mg/mL in water

  Acceptance criteria: −9° to −12°

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.
- **Labeling:** Label it to indicate that it is for veterinary use only.
- **USP Reference Standards** ⟨11⟩

USP Flunixin Meglumine RS

USP Flunixin Related Compound A RS

Chloronicotinic acid;
2-Chloronicotinic acid.
$C_6H_4ClNO_2$ 157.55

USP Flunixin Related Compound B RS

Trifluoromethyl toluidine;
2-Methyl-3-(trifluoromethyl)aniline.
$C_8H_8F_3N$ 175.15

USP Flunixin Related Compound C RS

Ethyl chloronicotinate;
Ethyl 2-chloronicotinate.
$C_8H_8ClNO_2$ 185.61

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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