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Flunixin Meglumine Injection

DEFINITION

Flunixin Meglumine Injection is a sterile solution of Flunixin Meglumine in Water for Injection. It contains the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of flunixin ($C_{14}H_{11}F_3N_2O_2$). It may contain phenol or another suitable preservative.

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** **Thin-Layer Chromatographic Identification Test ⟨201⟩**

Buffer: Dissolve 4.1 g of anhydrous sodium acetate in 500 mL of water. Add 2.9 mL of glacial acetic acid, and dilute with water to 1000 mL.

Standard solution: 3 mg/mL of USP Flunixin Meglumine RS in methanol

Sample solution: Transfer the equivalent to 50 mg of flunixin from Injection to a 50-mL centrifuge tube. Add 10 mL of *Buffer*, and extract with 25 mL of ethyl acetate. Use the upper phase as the *Sample solution*.

Chromatographic system

Adsorbent: Silica gel

Application volume: 10 µL

Developing solvent system: Toluene, ethyl acetate, glacial acetic acid, and water (75:25:10:1)

Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

Mobile phase: Methanol, water, and acetic acid (70:30:1)

Diluent: Methanol and water (70:30)

System suitability solution: 0.33 mg/mL of USP Flunixin Meglumine RS and 0.02 mg/mL of phenol in *Diluent*

Standard solution: 0.33 mg/mL of USP Flunixin Meglumine RS in *Diluent*

Sample solution: Transfer an amount of Injection equivalent to 500 mg of flunixin to a 250-mL volumetric flask, and dilute with *Diluent* to volume. Further dilute this solution with *Diluent* to obtain a solution containing 0.2 mg/mL of flunixin. Pass a portion of this solution through a filter of 0.45-µm or finer pore size, discarding the first few mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

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

Column temperature: 30° ± 2°

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 17 between phenol and flunixin meglumine

Tailing factor: NMT 2.0 for flunixin meglumine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of flunixin ($C_{14}H_{11}F_3N_2O_2$) in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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 = nominal concentration of flunixin in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of flunixin, 296.25

M_{r2} = molecular weight of flunixin meglumine, 491.46

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Change to read:

• **Organic Impurities**

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

Sensitivity solution: 0.167 µg/mL of USP Flunixin Meglumine RS in *Diluent*▲ (ERR 1-Mar-2020)

System suitability

Samples: *System suitability solution* and *Sensitivity solution*

Suitability requirements

Resolution: NLT 17 between phenol and flunixin meglumine, *System suitability solution*

Tailing factor: NMT 2.0, *System suitability solution*

Relative standard deviation: NMT 10.0%, *Sensitivity solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Sample solution* and *Sensitivity solution*

Calculate the percentage of each impurity in the portion of Injection taken:

$$\text{Result} = (r_U/r_T) \times 100$$

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

r_T = sum of all the peak responses from the *Sample solution*

Acceptance criteria: See *Table 1*. Disregard any peak less than the response of the flunixin meglumine peak as obtained from the *Sensitivity solution* (0.05%). Disregard the peak due to phenol, if present, which elutes at a relative retention time of 0.25 with respect to flunixin.

Table 1

Name	Acceptance Criteria, NMT (%)
Any unspecified impurity	1.0
Total impurities	2.0

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 4.54 USP Endotoxin Units/mg of flunixin

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

• **pH ⟨791⟩:** 7.8–9.0

• **Particulate Matter in Injections ⟨788⟩:** Meets requirements if labeled for IV use

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in multiple-dose containers, and store between 2° and 30°.

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

• **USP Reference Standards ⟨11⟩**

USP Flunixin Meglumine RS

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

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

Chromatographic Database Information: Chromatographic Database

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