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Flunixin Meglumine Paste

» Flunixin Meglumine Paste contains an amount of flunixin meglumine ($C_{14}H_{11}F_3N_2O_2 \cdot C_7H_{17}NO_5$) equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of flunixin ($C_{14}H_{11}F_3N_2O_2$).

Packaging and storage—Preserve in a well-closed container.

USP Reference standards ⟨11⟩—

USP Flunixin Meglumine RS

Labeling—Label the Paste to indicate that it is for veterinary use only.

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, both relative to the internal standard, as obtained in the *Assay*.

Microbial enumeration tests ⟨61⟩ and **Tests for specified microorganisms ⟨62⟩**—It meets the requirements of the tests for absence of *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, and *Salmonella* species.

Assay—

Mobile phase—Prepare a filtered and degassed mixture of methanol, water, and glacial acetic acid (70:30:1). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Internal standard solution—Dissolve a quantity of sodium benzoate in water to obtain a solution containing 33 mg per mL.

Diluent—Prepare a mixture of methanol and water (7:3).

Standard preparation—Transfer about 83 mg of USP Flunixin Meglumine RS, accurately weighed, to a 50-mL centrifuge tube. Add 5.0 mL of *Internal standard solution*, 20.0 mL of water, and 10.0 mL of methanol to the tube, and mix to dissolve. Transfer 10.0 mL of this solution to a 25-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Assay preparation—Transfer an accurately weighed quantity of Paste, equivalent to about 50 mg of flunixin, to a 50-mL centrifuge tube. Add 5.0 mL of *Internal standard solution* and 20.0 mL of water to the tube, and rotate for 20 minutes. Add 10.0 mL of methanol, and mix. Heat the tube in a water bath at 60° for 5 minutes, with occasional shaking. Continue rotating the tube until cool, and centrifuge. Transfer 10.0 mL of the clear supernatant to a 25-mL volumetric flask, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.5 for sodium benzoate and 1.0 for flunixin meglumine; the resolution, *R,* between sodium benzoate and flunixin meglumine is not less than 1.9; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of flunixin ($C_{14}H_{11}F_3N_2O_2$) in the portion of Paste taken by the formula:

$$(296.25/491.46)(87.5C)(R_U/R_S)$$

in which 296.25 and 491.46 are the molecular weights of flunixin and flunixin meglumine, respectively; C is the concentration, in mg per mL, of USP Flunixin Meglumine RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak responses for flunixin and sodium benzoate obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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