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Flunixin Meglumine Granules

» Flunixin Meglumine Granules contain 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 well-closed containers.

Labeling—Label Granules to indicate that they are for veterinary use only.

USP Reference standards ⟨11⟩—

USP Flunixin Meglumine RS

Identification—

A: The UV absorption spectrum of the solution employed for measurement of absorbance in the *Assay* exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Flunixin Meglumine RS, concomitantly measured.

B: Grind a quantity of Granules, equivalent to about 25 mg of flunixin, and transfer the powder to a 50-mL centrifuge tube. Add 20 mL of acetate buffer, prepared by dissolving 4.1 g of anhydrous sodium acetate in 500 mL of water, adding 2.9 mL of glacial acetic acid, and diluting with water to 1000 mL. Rotate the tube for 10 minutes. Extract with 25 mL of ethyl acetate, and use the upper phase as the test solution. Separately apply 10 µL of the test solution and 10 µL of a Standard solution of USP Flunixin Meglumine RS in methanol containing 1.5 mg per mL to a thin-layer chromatographic plate (see *Chromatography ⟨621⟩*) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatograms in a solvent system consisting of a mixture of toluene, ethyl acetate, glacial acetic acid, and water (65:30:10:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the spots to air-dry. Examine the plate under short-wavelength UV light: the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the *Standard solution*.

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

Procedure—Transfer a quantity of Granules, equivalent to about 12.5 mg of flunixin, to the dissolution flask. Determine the amount of flunixin ($C_{14}H_{11}F_3N_2O_2$) dissolved from UV absorbances at the wavelength of maximum absorbance at about 252 nm on filtered portions of solution under test in comparison with a Standard solution having a known concentration of about 23.6 µg per mL of USP Flunixin Meglumine RS in the same *Medium*. Each µg of flunixin meglumine is equivalent to 0.6028 µg of flunixin.

Tolerances—Not less than 75% *(Q)* of the labeled amount of flunixin ($C_{14}H_{11}F_3N_2O_2$) is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩—meet the requirements.

Assay—

Standard preparation—Dissolve an accurately weighed quantity of USP Flunixin Meglumine RS in water, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 0.82 mg per mL. Transfer 4.0 mL of this solution to a 100-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix.

Assay preparation—Dissolve an accurately weighed quantity of Granules in water by shaking for 30 minutes. Quantitatively dilute with water to obtain a solution containing about 0.5 mg of flunixin per mL, and mix. Centrifuge a portion of this solution. Transfer 4.0 mL of the supernatant layer to a 100-mL volumetric flask, dilute with 0.1 N sodium hydroxide to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparation* at the wavelength of maximum absorbance at about 283 nm using 0.1 N sodium hydroxide to set the instrument. Calculate the quantity, in mg, of flunixin ($C_{14}H_{11}F_3N_2O_2$) in the portion of Granules taken by the formula:

$$(296.25/491.46)(12{,}500C)(A_U/A_S)$$

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 A_U and A_S are the absorbances of 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 GRANULES	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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