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Cephapirin Sodium Intramammary Infusion

» Cephapirin Sodium Intramammary Infusion is a suspension of Cephapirin Sodium in a suitable vegetable oil vehicle. It contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled quantity of cephapirin ($C_{17}H_{17}N_3O_6S_2$). It contains a suitable dispersing agent.

Packaging and storage—Preserve in well-closed unit-dose disposable syringes at controlled room temperature.

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

USP Reference standards ⟨11⟩—
USP Cephapirin Sodium RS

Change to read:

▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: 197K▲ (CN 1-May-2020) —Prepare the test specimen as follows. Transfer the contents of 1 syringe of Intramammary Infusion to a 50-mL centrifuge tube, add 25 mL of toluene, mix for about 1 minute, and centrifuge. Remove and discard the toluene layer without disturbing the residue in the centrifuge tube. Wash the residue with two 25-mL portions of toluene. Dry the residue in vacuum at 60°, and use the dried residue as the test specimen. Mix the dried residue with 9 parts of potassium bromide, and record the IR spectrum, using the diffuse reflectance technique: the IR absorption spectrum so obtained corresponds to that of a similar dispersion of USP Cephapirin Sodium RS in potassium bromide.

Water Determination, *Method I* ⟨921⟩ **:** not more than 1.0%, 10 mL of Intramammary Infusion being tested.

Assay—

Solution A, Solution B, Mobile phase, Extraction solution, Dilution buffer, 10% Acetic acid solution, System suitability solution, Standard preparation, and *Chromatographic system*—Proceed as directed in the *Assay* under *Cephapirin Benzathine*.

Assay preparation—Express the entire contents of a syringe of the Intramammary Infusion into a centrifuge tube. For each mL of Intramammary Infusion, add 1.0 *n*-heptane and 1.0 mL of *Extraction solution,* cap, and mix on a vortex mixer at high speed for 5 minutes. Centrifuge for 5 minutes at a speed sufficient to break the emulsion. Remove the aqueous layer, and pass through a 0.45-µm nylon filter, discarding the first 0.5 mL. Transfer 2.5 mL of the filtered aqueous phase into a 25-mL volumetric flask that contains a solution composed of 15.0 mL of *Dilution buffer* and 7.0 mL of acetonitrile. Add water to volume, and mix well to obtain a single phase.

Procedure—Separately inject equal volumes (about 2 µL) of the duplicate *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas of the major peaks. Calculate the quantity, in mg, of cephapirin ($C_{17}H_{17}N_3O_6S_2$) in each syringe of Intramammary Infusion taken by the formula:

$$10PW(V_U/V_S)(r_U/r_S)$$

in which P is the assigned potency, in µg of cephapirin per mg, of USP Cephapirin Sodium RS; W is the quantity of USP Cephapirin Sodium RS, in mg, used to prepare the *Standard preparation;* V_S is the final volume, in mL, of the *Standard preparation;* V_U is the entire volume of Intramammary Infusion, in mL, in one syringe; and r_U and r_S are the peak area and the average peak area of the cephapirin peaks obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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Topic/Question	Contact	Expert Committee
CEPHAPIRIN SODIUM INTRAMAMMARY INFUSION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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