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Delete the following:

▲Aminopentamide Sulfate Injection

» Aminopentamide Sulfate Injection is a sterile solution of Aminopentamide Sulfate in Water for Injection. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of aminopentamide sulfate ($C_{19}H_{24}N_2O \cdot H_2SO_4$).

Packaging and storage—Preserve in tight, single-dose or multiple-dose *Containers for Injections*, as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging*. Store at controlled room temperature.

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

USP Reference standards ⟨11⟩—
USP Aminopentamide Sulfate RS

Identification—Transfer 10 mL of the Injection to a separator, add sodium hydroxide TS until alkaline to litmus, and extract with 25 mL of chloroform. Transfer a few drops of the chloroform extract to a KRS-5 plate, and allow to dry. Record the IR absorption spectrum by the attenuated total reflectance technique (see *Mid-Infrared Spectroscopy* ⟨854⟩). The spectrum thus obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Aminopentamide Sulfate RS, concomitantly measured.

Bacterial Endotoxins Test ⟨85⟩ — It contains not more than 25 USP Endotoxin Units per mg of aminopentamide sulfate.

Sterility Tests ⟨71⟩ — It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH ⟨791⟩: between 2.5 and 4.5.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

Mobile phase—Transfer 14.4 g of sodium lauryl sulfate to a 500-mL volumetric flask, add 100 mL of glacial acetic acid, dilute with water to volume, mix, and pass through a filter having a 0.5-µm or finer porosity. Transfer 50 mL of this solution to a 1000-mL volumetric flask, add 350 mL of methanol and 350 mL of acetonitrile, dilute with water to volume, and mix. Filter and degas before use. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Aminopentamide Sulfate RS in water to obtain a solution having a known concentration equivalent to the labeled concentration of aminopentamide sulfate in the Injection.

Assay preparation—Use the undiluted Injection.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1 and is maintained at a constant temperature of about 40°. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.5; and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of aminopentamide sulfate ($C_{19}H_{24}N_2O \cdot H_2SO_4$) in each mL of the Injection taken by the formula:

$$C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Aminopentamide Sulfate RS in the *Standard preparation*; and r_U and r_S are the aminopentamide peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.▲ (USP 1-Dec-2024)

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

Topic/Question	Contact	Expert Committee
AMINOPENTAMIDE SULFATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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