Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-Dec-2024
Document Type: USP Monographs
DocId: GUID-321C02A7-B26A-4E65-BA97-93A9D3C39434_2_en-US
DOI: https://doi.org/10.31003/USPNF_M3050_02_01
DOI Ref: 91e8r

Delete the following:

▲Aminopentamide Sulfate Tablets

» Aminopentamide Sulfate Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of aminopentamide sulfate ($C_{19}H_{24}N_2O \cdot H_2SO_4$).

Packaging and storage—Preserve in tight containers, and store at controlled room temperature.

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

USP Reference standards ⟨11⟩—
USP Aminopentamide Sulfate RS

Identification—Transfer a portion of ground Tablet powder, equivalent to about 2 mg of aminopentamide, to a separator, add 20 mL of water and 3 mL of 10 N sodium hydroxide, and mix. Extract with two 20-mL portions of methylene chloride, and evaporate the combined methylene chloride extracts to a volume of about 0.5 mL. Transfer a few drops of the chloroform concentrate 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.

Disintegration ⟨701⟩: not more than 10 minutes, simulated gastric fluid TS being substituted for water in the test.

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

Loss on drying ⟨731⟩: Dry about 1 g of powdered Tablets, accurately weighed, in vacuum at a pressure of 5 mm of mercury or less at 60° for 3 hours: it loses not more than 4.0% of its weight.

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 *Mobile phase* to obtain a solution having a known concentration of about 0.02 mg per mL.

Assay preparation—Weigh and finely powder not fewer than 10 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 0.2 mg of aminopentamide, to a suitable flask. Add 10.0 mL of *Mobile phase*, sonicate for 5 minutes, and stir by mechanical means for about 10 minutes. Pass this mixture through a filter having a 0.5-µm or finer porosity, discarding the first 5 mL of the filtrate. Use the clear filtrate as the *Assay preparation*.

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 column efficiency is not less than 900 theoretical plates; and the relative standard deviation for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 50 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 the portion of Tablets taken by the formula:

$$10C(r_U/r_S)$$

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 TABLETS	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(3)

Current DocID: GUID-321C02A7-B26A-4E65-BA97-93A9D3C39434_2_en-US

DOI: https://doi.org/10.31003/USPNF_M3050_02_01

DOI ref: 91e8r