Amikacin Sulfate

C$_{22}$H$_{43}$N$_5$O$_{13}$ · H$_2$SO$_4$  762.15
C$_{22}$H$_{43}$N$_5$O$_{13}$ · 2H$_2$SO$_4$  781.76

**α**-3-Amino-3-deoxy-α-D-glucopyranosyl(1→6)-O-[6-amino-6-deoxy-α-D-glucopyranosyl(1→4)]-N'-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-, (S)-, sulfate (1:2 or 1:1.8) (salt).

O-3-Amino-3-deoxy-α-D-glucopyranosyl(1→4)-O-6-amino-6-deoxy-α-D-glucopyranosyl(1→6)-N'-(4-amino-2-hydroxy-ybutyryl)-2-deoxy-α-streptamine sulfate (1:2 or 1:1.8) [39831-55-5].

» Amikacin Sulfate having a molar ratio of amikacin to H$_2$SO$_4$ of 1:2 contains the equivalent of not less than 674 µg and not more than 786 µg of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$) per mg, calculated on the dried basis; Amikacin Sulfate having a molar ratio of amikacin to H$_2$SO$_4$ of 1:1.8 contains the equivalent of not less than 691 µg and not more than 806 µg of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$) per mg, calculated on the dried basis.

**Packaging and storage**—Preserve in tight containers.

**Labeling**—Label it to indicate whether its molar ratio of amikacin to H$_2$SO$_4$ is 1:2 or 1:1.8.

**USP Reference standards** (11)—
- USP Amikacin RS
- USP Kanamycin Sulfate RS

**Identification**—It responds to the Identification tests under Amikacin.

**Specific rotation** (781S): between +76° and +84°.

Test solution: 20 mg per mL, in water.

**Crystallinity** (695): meets the requirements.

**pH** (791): between 2.0 and 4.0 (1:2 salt), or between 6.0 and 7.3 (1:1.8 salt), in a solution containing 10 mg per mL.

**Loss on drying** (781)—Dry about 100 mg, accurately weighed, in vacuum at a pressure not exceeding 5 mm of mercury at 110° for 3 hours: it loses not more than 13.0% of its weight.

**Residue on ignition** (281): not more than 1.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

**Assay**—

Mobile phase, System suitability solution, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under Amikacin.

Assay preparation—Transfer an accurately weighed quantity of Amikacin Sulfate, equivalent to about 50 mg of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$), to a 250-mL volumetric flask, add about 50 mL of water, and swirl to dissolve. Dilute with water to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with water to volume, and mix.

**Procedure**—Proceed as directed in the Assay under Amikacin. Calculate the quantity, in µg, of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$) in each mg of Amikacin Sulfate taken by the formula:

$$2500(CE / W)(r_U / r_S)$$

in which $W$ is the weight, in mg, of Amikacin Sulfate taken to prepare the Assay preparation; and the other terms are as defined therein.

Amikacin Sulfate Injection

» Amikacin Sulfate Injection is a sterile solution of Amikacin Sulfate in Water for Injection, or of Amikacin in Water for Injection prepared with the aid of Sulfuric Acid. It contains not less than 90.0 percent and not more than 120.0 per cent of the labeled amount of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$).

**Packaging and storage**—Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type III glass.

**USP Reference standards** (11)—
- USP Amikacin RS
- USP Endotoxin RS
- USP Kanamycin Sulfate RS

**Identification**—

A: Dilute it with water to obtain a solution containing 6 mg per mL: the resulting solution meets the requirements of Identification test A under Amikacin.

B: The retention time of the peak for amikacin in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay.

**Bacterial endotoxins** (85)—It contains not more than 0.33 USP Endotoxin Unit per mg of amikacin.

**pH** (791): between 3.5 and 5.5.

**Particulate matter** (788): meets the requirements for small-volume injections.

**Other requirements**—It meets the requirements under Injections (1).

**Assay**—

Mobile phase, System suitability solution, Standard preparation, and Chromatographic system—Proceed as directed in the Assay under Amikacin.

Assay preparation—Dilute an accurately measured volume of Injection quantitatively, and stepwise if necessary, with water to obtain a solution having a concentration of about 0.02 mg of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$) per mL.

**Procedure**—Proceed as directed in the Assay for Amikacin. Calculate the quantity, in mg, of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$) in each mL of the Injection taken by the formula:

$$(L / D)(CE / 1000)(r_U / r_S)$$

in which $L$ is the labeled quantity, in mg, of amikacin in each mL of Injection; $D$ is the concentration, in mg per mL, of amikacin (C$_{22}$H$_{43}$N$_5$O$_{13}$) in the Assay preparation, on the basis of the labeled quantity per mL and the extent of dilution; and the other terms are as defined therein.