

Kanamycin sulphate

Meets USP and JP testing specifications

Product Code: TC136M

Product Description :

Molecular weight: 582.58

Molecular formula: $C_{18}H_{36}N_4O_{11}.H_2SO_4$

CAS No.: 25389-94-0

Quality Control:

Appearance (USP, JP)

White crystalline powder

Solubility (USP)

Freely soluble in water; insoluble in acetone, in ethyl acetate and in benzene

Solubility (JP)

It is freely soluble in water and practically insoluble in ethanol (99.5%)

Identification A : FTIR (USP)

Matches with the standard pattern

Identification 1 (JP)

A blue-purple colour develops

Identification B : Sulfate (USP)

Meets the requirements

Identification 2 (JP)

The principal spot obtained from the sample solution and the spot obtained from the standard solution show a purple-brown colour and the same R_f value

Identification C (USP)

The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay

Identification 3 (JP)

A white precipitate is formed

pH (1% in water at 25°C) (USP)

6.50 - 8.50

Optical rotation (JP)

+112.00° to +123.00° (1% in water at 20°C)

Organic impurity (USP)

The chromatograms show principal spots at the same R_f value and no secondary spot, if present from the sample solution, is more intense than the principal spot of standard solution 2

Related substance : TLC (JP)

The spot other than the principal spot obtained from the sample solution is not more intense than the spot from the standard solution

Crystallinity (USP)

Meets the requirements

Sulphuric acid : sulphate (JP)

15.0 - 17.0% (on dried basis)

Residue on ignition (USP)

≤ 1.00%

Residue on ignition (JP)

≤ 0.50%

Arsenic (JP)

≤ 0.0001%

Heavy metals (JP)

≤ 0.0010%

Loss on drying (USP, JP)

≤ 4.00% (at 60°C at a pressure not exceeding 5 mm of mercury for 3 hr)

Potency : System suitability : Resolution (USP)

≥ 3.00

Potency : System suitability : Relative standard deviation (USP)

≤ 2.00%

Potency (USP)

min. 750 µg/mg (on dried basis)

Potency (JP)

750 - 832 µg/mg (on dried basis)

Bacterial endotoxins (USP)

≤ 0.67 USP EU/mg of kanamycin

Sterility (USP)

Complies

Storage and Shelf Life:

Store at 2 - 8°C away from bright light.

Shelf life is 36 months.

Use before expiry date given on the product label.

Revision : 02/2022

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