

PRODUCT SPECIFICATION

Product : Neomycin Sulphate

Characters : Appearance – white or yellowish-white powder,

hygroscopic.

Solubility – very soluble in water, very slightly Soluble in alcohol, practically insoluble in acetone.

Identification : A (1) The retention time of a major peak meets the

the requirements. (2) Impurity C: conform.

B Positive

pH : 5.0 - 7.5

Specific optical rotation : +53.5° - +59.0°

Related substances : Impurity A: NMT 2.0 %

Impurity C: 3 – 15 %

Any other impurity: NMT 5 %

Total of other impurities: NMT 15 %

Sulfate (anhydrous) : 27.0 – 31.0 %

Loss on drying : NMT 8.0 %

Sulfated ash : NMT 1.0 %

Potency : NLT 680 IU/mg (dried substance)

MSDS : available upon request