

PRODUCT SPECIFICATION

Product : **Gentamycin Sulphate Sterile**

Characters : a white or almost white powder, freely soluble in water,

practically insoluble in alcohol and in ether.

Identification : tests according to monograph

Appearance of solution : clear and not more intensely colored than degree 6 of

the range of reference solutions of the most appropriate

colour.

pH : 3.5 to 5.5

Specific optical rotation : +107° to +121°

Methanol : NMT 1.0 %

Composition : C1 - 25.0 to 50.0 %

C1A: 10.0 to 35.0 % C2A + C2: 25.0 to 55.0 %

Water : NMT 15.0 %

Sulphated ash : NMT 1.0 %

Sulphate : 32.0 to 35.0 %

Sterility : complies with the test for sterility

Bacterial endotoxins : less than 1.67 IU/mg

Assay : not less than 590 IU/mg (anhydrous substance)

MSDS : available upon request