

PRODUCT SPECIFICATION

Product : **Dihydrostreptomycin Sulfate Sterile**
(for veterinary use)

Characters	:	a white or almost white powder, freely soluble in water, practically insoluble in acetone, in alcohol and in methanol. It may be hygroscopic.
Identification	:	A. The retention time of a major peak meets the Requirements. E. Positive
Appearance of solution	:	Colour: not more intensely coloured than 5 Clarity: not more opalescent than II
pH	:	5.0 – 7.0
Specific optical rotation	:	-83.0° - -91.0°
Related substances	:	Impurity A: NMT 1.0 % Impurity B: NMT 1.0 % Impurity C: NMT 2.0 % Any other impurity: NMT 1.0 % Total of impurities: NMT 5.0 %
Heavy metals	:	NMT 20 ppm
Loss on drying	:	NMT 5.0 %
Sulfated ash	:	NMT 1.0 %
Bacterial endotoxins	:	less than 0.50 IU/mg
Abnormal toxicity	:	meets the requirements
Content (HPLC)	:	sum of Dihydrostreptomycin Sulfate and Streptomycin Sulfate: 95.0 % - 102.0 % Streptomycin Sulfate: NMT 2.0 % (dried substances)
Sodium Metabisulfite limit	:	NMT 0.4 % (internal)
Potency	:	NLT 730 IU/mg (dried substances)
Bacterial endotoxins	:	less than 0.50 IU/mg
Sterility	:	meets the requirements