

## **PRODUCT SPECIFICATION**

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

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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)

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