

杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Dihydrostreptomycin sulfate(CAS 5490-27-7)

Batch No.: DR20140209	Piece: 1057kg
Manufacture Date: 2014.02.09	Expiry Date: 2018.02.08

TESTS:

Items	Specification	Results
Characteristics	A white or almost white powder, freely soluble in water, practically insoluble in acetone, in alcohol and in methanol. It may be hygroscopic.	Conforms
Identification	A: The retention time of a major peak meets the requirements. E: Positive	Conforms Positive
Appearance of solution	Not more intensely coloured than 5. Clarity: not more opalescent than II.	6 Clear -1/2
PH	5.0~7.0	5.7
Specific optical rotation	-83.0°~ -91.0°	-90.1°
Related substances	Impurity A: ≤1.0% Impurity B: ≤1.0% Impurity C: ≤2.0% Any other impurity: ≤1.0% Total impurities: ≤5.0%	0.28% 0.57% 1.2% 0.82% 3.6%
Heavy metals	≤20ppm	<20ppm
Loss on drying	≤5.0%	4.0%
Sulphated ash	≤1.0%	0.5%
Abnormal toxicity	Meets the requirements	Conforms
Content(HPLC)	Sum of dihydrostreptomycin sulphate and streptomycin sulfate: 95%~102.0% Streptomycin sulphate: ≤2.0%(dried basis)	95.9% N.D.
Sodium metabisulfate limit	≤0.4%(internal)	0.1%
Potency	≤730IU/mg(dried basis)	766IU/mg(dried substance) 735IU/mg(as is)
Bacterial endotoxins	<0.50IU/mg	<0.1IU/mg
Sterility	Meets the requirements	Conforms
Conclusion: The results conform with EP8.0.		



Analyst: _____ **Checker:** _____ **QA.Manager:** _____

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