

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

CERTIFICATE OF ANALYSIS

Gentamycin Sulfate Sterile

Batch No.: DR20130624	Batch Size: 500kg
CAS No.: 1405-41-0	Package: 8.334kg/tin,2tin/ctn
Manufacture Date: 2013.06.24	Expiry Date: 2017.05

TESTS:

Items	Specification	Results
Characteristics	A white or almost white powder, freely soluble in water, Practically insoluble in alcohol and in ether.	Conforms
Identification	Tests according to monograph	Conforms
Appearance of solution	Clear and not more intensely colored than degree 6 of the range of reference solutions of the most appropriate color.	Conforms
PH	3.5~5.5	4.5
Specific optical rotation	+107.0° ~ +121.0°	+114.0°
Methanol	≤ 1.0%	Conforms
Composition	C1 25.0%~50.0% C1a 10.0%~35.0% C2a+C2 25.0%~ 55.0%	30.7% 23.3% 46.0%
Water	≤ 15.0%	9.2%
Sulphated ash	≤ 1.0%	0.5%
Sulphate	32.0%~35.0%	34.5%
Sterility	Conforms with the test for sterility	Conforms
Bacterial endotoxins	≤ 1.67 IU/mg	<0.71 IU/mg
Assay	≥ 590 IU/mg	631 IU/mg(anhydrous substance) 573 IU/mg(hydrous substance)

Conclusion: The results conform with BP2002/EP4.0.

Checker: _____

QA.Manager: _____



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