

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

CERTIFICATE OF ANALYSIS

Capreomycin Sulfate

Batch No.: DR20120506	Piece: 300g
Manufacture Date: 2012.05.06	Expiry Date: 2015.05.14

TESTS:

Items	Specification	Results
Appearance	A white hygroscopic	Conforms
Identification	Responds to the test sulfate	Positive
PH(3% w/v,solution)	4.5~7.5	6.2
Loss on drying	≤10.0%	3.3%
Residue on ignition	≤3.0%	0.2%
Heavy metals	≤0.003%	<0.003%
Capreomycin I content	≥ 90.0%	94.1 %
Potency(on dried basis)	700~1050μg/mg	850 μg/mg
Sterility	Conforms	Conforms
Bacterial Endotoxins	≤ 0.35EU/mg	<0.25EU/mg

Conclusion: The results conform with USP 31.

Analyst: _____

Checker: _____

QA.Manager: _____



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