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

CERTIFICATE OF ANALYSIS

Kanamycin Sulfate Monohydrate

Batch No.: DR20130917	**Quantity:** 46.7kg
Manufacture Date: 2013.09.17	**Expiry Date:** 2016.09.16

TESTS:

Items	Specification	Results
Characters	A white or almost white,crystalline powder	Conforms
Identification	Conforms	Conforms
Crystallinity	--------	Lamellar ,flake,edges,angular,sharp, fractured,optical,almost colourless with yellowish,transparent,cracked
PH	6.5-8.5 (1% w/v)	7.8
Residue on ignition	≤1.0%	0.03%
Loss on drying	≤4.0% (60℃,≤0.7kpa,3h)	0.30%
Bacterial endotoxin	≤0.60EU/mg	Conforms
Bioburden	≤25cfu/g	Conforms
Chromatographic purity	≤3.0%	Conforms
Residual solvents	Ethanol ≤2000ppm	1430ppm
Assay and related substances	Assay (on dried basis)≥750μg/mg	771μg/mg
	Kanamycin B≤1.5%	0.6%
	Impurity 1≤1.2%	0.6%
	Impurity 2≤1.2%	0.2%
	Impurity 3≤1.2%	0.2%
	Total Impurities≤4.0%	1.7%
Conclusion: The results conform with USP and in-house standard.		

杭州东瑞医药科技有限公司 Hangzhou Dawn Ray Pharmaceutical Co.,Ltd. 质检专用章 QUALITY STAMP

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