

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

CERTIFICATE OF ANALYSIS

Besifloxacin HCL

Batch No.: DR20130218	Piece: 3000g
Manufacture Date: 2013.02.18	Expiry Date: 2016.02.17

TESTS:

Items	Specification	Results
Characteristics	White to off-white powder(or slight yellow)	A white crystalline powder
Identification	NMR,HPLC,IR	Conforms
Solubility	Slightly soluble in water,practically insoluble in diethyl ether.	Conforms
Loss on drying	≤1.0%	0.90%
Residue on ignition	≤0.5%	0.31%
Heavy metals	≤20ppm	Conforms
Purity	≥98.5%	99.52%
Assay	98.0%~102.0%	101.5%
Particle size	90% less than 20μm	Conforms
Residual solvents	Ethanol: ≤3000ppm	Conforms
	Chloroform ≤60ppm	Conforms
Related substance	Total impurities: ≤1.0%	0.46%
	Single impurity: ≤0.5%	0.13%

Conclusion: The results conform with Enterprise standard.



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