

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

CERTIFICATE OF ANALYSIS

Biapenem

Batch No.: DR20130413	Quantity: 23.6g
Manufacture Date: 2013.04.13	Expiry Date: 2014.04.12
Storage : keep cool and dry	

TESTS:

Items	Specification	Results
Appearance	White to light yellow crystalline powder, Odourless. slightly soluble in water ,Almost insoluble in methanol, ethanol and acetonitrile	White to light yellow crystalline powder, Odourless. slightly soluble in water ,Almost insoluble in methanol, ethanol and acetonitrile
Identification chemical reaction UV IR	Piositive Should have the largest wavelength absorption at 292-296 nm Shall conform to the reference substance of the solution	Piositive have the largest wavelength absorption at 294nm conform to the reference substance of the solution
Optical rotation	-28°~ -35°	-33°
PH	4.0-6.0	5.0
Clarity and color of solution	Conforms	Conforms
Related substance		
Total impurities	≤1.0%	0.2%
The biggest single impurity	≤0.5%	0.10%
Biapenem polymer	≤0.5%	0.2%
Methanol	≤0.3%	ND
Acetone	≤0.3%	ND
Acetonitrile	≤0.041%	ND
Dichloromethane	≤0.06%	ND
Tetrahydrofuran	≤0.072%	ND
Loss on drying	≤0.5%	0.08%
Residue on ignition	≤0.2%	0.1%
Heavy metals	≤10ppm	Conforms
Visible foreign matter	Conforms	Conforms
Insoluble particle	Conforms	Conforms

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Sterility	Conforms	Conforms
Bacterial endotoxin	<0.5EU/ mg	Conforms
Assay	98.0-102.0% of Biapenemon the dried basis	100.5%
Conclusion: The results conform with the standard.		



Analyst: Joe Yu **Checker:** Agnes Zhong **QA.Manager:** Sun Wenhui

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