

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

CERTIFICATE OF ANALYSIS

Tigecycline (CAS 220620-09-7)

Batch No.: DR20131002	Piece: 2.0kg
Manufacture Date: 2013.10.02	Expiry Date: 2015.10.01

TESTS:

Items	Specification	Results
Appearance	Orange to orange-red crystalline powder	Orange crystalline powder
Water	≤2.0%	0.83%
Solubility	Soluble in water, slightly soluble in ethanol ,very slightly soluble in and methanol	Conforms
Identification by A) IR B) HPLC	The infrared absorption spectrum is consistent with the spectrum of Tigecycline reference The retention times of the major peaks in the chromatogram of the assay preparation correspond to those of th standard preparation as obtained in the assay	Conforms
PH	7.0~8.5	7.9
Specific Rotation	-190° ~ -215°	-194°
Residue on ignition	≤0.1%	0.01%
Heavy metals	≤10ppm	Conforms
Related substance	9-amino-minocycline≤0.15% C-4 epimer≤1.0% Single individual impurity:≤0.1% Total impurities:≤1.5%	0.03% 0.31% 0.02% 0.45%
Residual solvents	Dichloromethane ≤0.06% Acetone ≤0.5% Methanol≤0.3% Isopropanol≤0.5% N-Methyl pyrrolidone≤0.053% Toluene≤0.089%	ND 0.39% ND ND ND ND
Bacterial endotoxins	<1.75EU/mg	Conforms
Microbial Limit	Total aerobic microbial count:≤100CFU/G	Conforms
Assay (HPLC)	98.0%~102.0% calculated on anhydrous basis	98.7%
Conclusion: The results conform with the in-house standard		



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

Add:1018 Guangyin Building No.42 E. Fengqi Road, Hangzhou, 310012 China

Tel:+86-571- 85335020

E-mail: agnes@dawnraypharma.com

Fax: +86-571- 86948329

Website: http://www.dawnraypharma.com/