



HANGZHOU DINGYAN CHEM CO., LTD
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CERTIFICATE OF ANALYSIS

NO: DYC081407241

Product name	Teicoplanin
CAS Number	61036-62-2
Molecule Formula	C88H95Cl2N9O33
Batch number	20140308
Manufacture Date	2014-03-08
Testing date	2014-03-08
Packing	5kg/Tin

Items	Standard	Result
Appearance	Yellow amorphous powder	Conform
Solubility	Freely soluble in water, sparingly soluble in dimethylformamide, insoluble in ethanol(96 percent V/V)	Conform
Identification	A. Infrared absorption B. HPLC	Conform
Appearance of solution	Clarity $\leq 1\#$ Color 80mg/ml, <BY3 or B4	Conform Conform
Acidity or alkalinity	6.5~7.5	7.1
Composition and related substances	Teicoplanin A2 group $\geq 80.0\%$ Teicoplanin A2-2 35.0~55.0% Teicoplanin A2-1 group $\leq 20.0\%$ Teicoplanin A2-3 group $\leq 20.0\%$ Teicoplanin A2-4 $\leq 20.0\%$ Teicoplanin A2-5 group $\leq 20.0\%$ Teicoplanin A3 group $\leq 15.0\%$ Total of impurities $\leq 5.0\%$	94.4% 49.7% 12.8% 8.8% 11.6% 11.6% 4.6% 1.0%
Impurity A	0.2% max	0.02%
Residual solvents	Ethanol $\leq 5000\text{ppm}$ Acetone $\leq 5000\text{ppm}$ Acetaldehyde $\leq 2000\text{ppm}$ Propionaldehyde $\leq 2000\text{ppm}$	33ppm 1620ppm 11ppm 5ppm
Sodium chloride	5.0% max	2.4%
Heavy metals	20ppm max	Conform
Water	15% max	2.7%
Sterility	Conform	Conform



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Bacterial endotoxins	<0.31 EU/mg	<0.31 EU/mg
Potency (dried substance)	≥ 900 IU/mg	1004 IU/mg
Conclusion	The specifications conform to EP8.1	

Hangzhou Dingyan Chem Co., Ltd.
QUALITY CONTROL: *Xuefen Chen* CHECK: 姚仙娟 INSPECTOR: 刘清风
Quality Control
Signature(s)