

Certificate of Analysis

Product Name	Teicoplanin		
Batch No.	20161029	Quantity	1kg
MFG. Date	Oct,29,2016	Retest. Date	Oct,28,2018
CAS No.	61036-62-2	Specs	EP8.1

ITEMS	SPECIFICATION	RESULTS
Appearance	Light yellow amorphous powder	Conforms
Solubility	Freely soluble in water, sparingly soluble in dimethylformamide, insoluble in ethanol(96 percent v/v)	Conforms
IR identification	IR spectrum of the test specimen should consistent with the IR spectrum of reference standard	Conforms
HPLC identification	The retention time of the principal peak is similar to which in the reference solution	Conforms
Appearance of solution(80mg/ml)	Clarity of solution ≤1#	Conforms
	Color of solution ≤BY3 or B4	
Water	≤15%	2.8%
PH	6.5-7.5	6.86
Heavy metals	≤20ppm	Conforms
Sodium chloride	≤5.0%	4.0%
Teicoplanin A2 group	≥80.0%	92.5%
A2-2 Teicoplanin	35.0% to 55.0%	40.7%
A2-1	≤20.0%	9.1%
A2-3	≤20.0%	10.2%
A2-4	≤20.0%	14.5%
A2-5	≤20.0%	18.0%
A3	≤15%	4.5%



Quality Control: Leonard Xiang Analyst: Anna Wen QA. Manager: Xu Min

Impurity A	≤0.2%	0.01%
Total impurities	≤5.0%	2.9%
Bacterial endotoxins	≤0.31 EU/mg	Conforms
Assay(dried substance)	≥900IU/mg	980IU/mg
Conclusion	Up to the Standard(EP8.1)	
Remarks		
Storage	Store in 2-8degC . Keep container tightly closed in a dry and well-ventilated place.	

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