

CERTIFICATE OF ANALYSIS

Product Name:	Teicoplanin		
Batch No.	1907004		
Packing	2kg/Tin	Manufacturing Date	July 19, 2019
Quantity	12.985kg	Expiry Date	July 18, 2021
Storage Conditions	Preserve in airtight containers, protect from light and store at 2 ~ 8°C		
Analytical Results			
Items	Specifications		Results
Characters	Yellowish, amorphous powder		Complies
Solubility	Freely soluble in water, sparingly soluble in dimethylformamide, insoluble in ethanol(96 percent v/v)		Complies
Identification	IR: IR spectrum of the test specimen should consistent with the IR spectrum of reference standard		Complies
	HPLC: The retention time of the principal peak is similar to which in the reference solution		Complies
Appearance of solution	Clarity of solution ≤ 1#		Complies
	Colour of solution < BY3 or B4		Complies
PH	6.5~7.5		6.95
Components	Teicoplanin A2 group	84.0 ~ 93.0%	90.70%
	Teicoplanin A2-1 group	10.0 ~ 19.0%	12.90%
	RRT about 0.85(RS3)	0.5 ~ 5.5%	3.80%
	RRT about 0.88(RS4)	0.5 ~ 4.0%	2.60%
	RRT about 0.93(A2-1)	2.0 ~ 7.0%	3.30%
	Teicoplanin A2-2	37.0 ~ 50.0%	47.00%
	RRT about A2-3 group	5.0 ~ 11.0%	7.20%
	RRT about 1.03(A2-3)	4.0 ~ 8.5%	5.10%
	RRT about A2-4	7.0 ~ 15.0%	11.80%
	RRT about A2-5 group	7.0 ~ 17.0%	11.80%
	RRT about 1.15 (A2-5)	7.0 ~ 15.0%	10.30%
	Teicoplanin A3 group	4.0 ~ 12.0%	8.00%
	Related substances	RRT about 1.25(RS1) ≤ 1.5%	
RRT about 1.30 (RS2) ≤ 1.5%			0.95%
RRT about 1.38 ≤ 2.5%			N.D
Any non-teicoplanin like impurity ≤ 0.5%			0.35%
Impurity A (RRT about 0.6) ≤ 0.2%			N.D
Total impurities ≤ 5.0%			1.30%
Residual solvents	Acetone ≤ 5000ppm		582ppm
	Ethanol ≤ 5000ppm		787ppm
Sodium chloride	≤ 5.0%		2.60%
Heavy metals	≤ 20ppm		Complies
Water(K.F)	≤ 15.0%		10.20%
Microbial limit test	TAMC ≤ 1000cfu/g		1 cfu/g
	TYMC ≤ 1000cfu/g		N.D
Potency(Anhydrous and Bacterial endotoxins)	≥ 900 IU/mg		1010 IU/mg
	< 0.31 EU/mg		Complies
Conclusion	This product complies with current Ph.Eur and EMA proposed specifications		

Inspector: Carlifor Wu

Verifier: Jack He

