



Taizhou Creating Bio-pharm Co., Ltd.

ADD: 715 Room, Unit A, Junyue Building, Taizhou, Zhejiang, China

TEL: 0086-576-88827176

FAX: 0086-576-88822496

## 分析证明书

## CERTIFICATE OF ANALYSIS

Product name 品名: Teicoplanin 替考拉宁 (非无菌)	
Batch no. 批号: 20220210	Quantity 数量: 500G
Manuf. date 生产日期: 2022/02/15	Expiry date 有效期: 2024/02/15

ITEMS	Standard	Results
Characteristics	Yellowish, amorphous powder.	Complies
Identification	IR conforms HPLC, the principal peaks (teicoplanins A3-1, A2-1, A2-2, A2-3, A2-4, and A2-5) in the chromatogram obtained with the test solution are similar in retention time and size to the principal peaks in the chromatogram obtained with reference solution (a).	Complies
Appearance of solution	The solution is clear and not more intensely coloured than reference solution BY <sub>3</sub> or B <sub>4</sub>	Complies
pH	6.5-7.5.	7.2
Composition and related substances	teicoplanin A 2 group: $\geq 80.0\%$ ; teicoplanin A 2-2: 35.0%-55.0%; teicoplanin A 2-1 group: $\leq 20.0\%$ ; teicoplanin A 2-3 group: $\leq 20.0\%$ ; teicoplanin A 2-4: $\leq 20.0\%$ ; teicoplanin A 2-5 group: $\leq 20.0\%$ ; teicoplanin A 3 group: $\leq 15.0\%$ ; total of impurities other than mesityloxy with a relative retention more than 1.25: $\leq 5.0\%$	94.0% 43.6% 13.5% 14.9% 14.2% 7.9% 4.8% 1.2%
Chlorides	$\leq 5\%$	0.2%
Water	$\leq 15.0\%$	1.4%
Impurity A	$\leq 0.2\%$	0.02%
Assay (anhydrous and sodium chloride-free substance)	$\geq 900\text{IU/mg}$ .	1054IU/mg
Bacterial endotoxin	$< 0.31\text{IU/mg}$	$< 0.31\text{IU/mg}$
Microbial limits TAMC	$\leq 10\text{cfu/g}$	1cfu/g
Residual solvents	Methanol $\leq 3000\text{ppm}$	39ppm
	Ethanol $\leq 5000\text{ppm}$	1417ppm
	Acetone $\leq 5000\text{ppm}$	2491ppm
Conclusion: Complies with Ph.Eur.9.0		

复核人 Checker:

化验人 Analyst:

