

分析证明书

CERTIFICATE OF ANALYSIS

Product name: Teicoplanin (sterile)替考拉宁	
Batch no. 批号:20180910	Quantity 数量: 15KG
Manuf. date 生产日期: 2018/09/25	Expiry date 有效期: 2020/09/25

ITEMS	Standard	Results
Characteristics	A white to light yellowish white powder.	A light yellowish white powder
Identification	IR	Conforms
Color and clarity of solution	Conforms	Conforms
pH(0.5g/10ml)	6.3-7.7	7.0
Sodium chloride	5.0% max.	4.0%
Water(K.F)	15.0% max.	4.8%
Heavy Metals	Less than 20ppm	<20PPM
Active component	TA2 80.0%min.	95.0%
	TA3 15.0% max.	3.8%
	Other 5.0% max.	1.8%
Bacterial endotoxins	Less than 0.75EU/mg	Conforms
Sterility	Conforms	Conforms
Residual solvents		
1. Acetone	10000ppm Max	6815ppm
2. Ethanol	5000ppm Max	4032ppm
Potency	Not less than 900 $\mu$ g/mg ,calculated on the anhydrous, de-sodium chloride and de-residual solvents basis	943ug/mg
Conclusion: Comply with the standard of JP15.		

复核人 Checker:

化验人 Analyst: