



# Certificate of analysis

Product name: Teicoplanin (non-sterile)

Cas number:61036-62-2

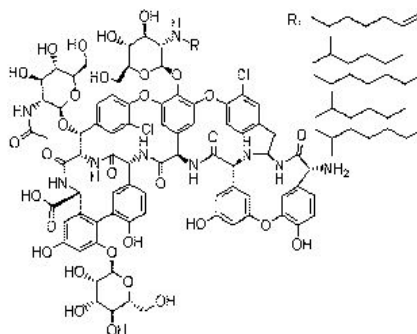
Molecular Formula: C<sub>77</sub>H<sub>77</sub>N<sub>9</sub>O<sub>31</sub>Cl<sub>2</sub>R

Molecular Weight: 1709.39

Date of production:Jul.16,2013

Batch NO:20130716

EXP. Date:Jul.15,2015



Chemical structure:

Items	Specifications	Results
Characteristics	A white to light yellowish white powder. It is freely soluble in water, sparingly soluble in N,N-dimethylformamide, and practically insoluble in acetonitrile, in methanol, in ethanol, in acetone, in acetic acid and in diethyl ether.	Conforms
Identification	1. color reaction with ninhydrin 2. color reaction with anthrone 3. IR spectrum	Conforms
Color and clarity of solution	Conforms with the stipulation in JP14	Conforms
pH(0.5g/10ml)	6.3-7.7	7.2
Bacterial endotoxins	Less than 0.73EU/mg	Conforms
Sodium chloride	5.0% max.	1.5%
Water(K.F)	15.0% max.	9.10%
Heavy Metals	Less than 20ppm	<20PPM
Arsenic	Less than 2ppm	<2PPM
Residual solvents		
1. Acetone	5000ppm Max	0 ppm
2. Ethanol	3000 ppm Max	0 ppm
3. Methanol	3000ppm Max	Absence
Active component	TA2 80.0%min. TA3 15.0% max. Other 5.0% max.	95.2% 3.0% 2.9%
Assay(potency)	Not less than 900 μg/mg, calculated on the anhydrous, de-sodium chloride and de-residual solvents basis	978ug/mg

**Conclusion: It complies with the JP15 standard**

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F

