



Certificate of analysis

Productname: Oxaliplatin

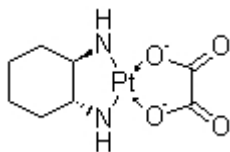
Cas number: 61825-94-3

Molecular Formula: C₈H₁₂N₂O₄Pt

Molecular Weight: 395.27

Date of production: Aug. 25, 2012

Chemical structure:



Items	Standard	Results
Description	White or almost white crystalline powder	Complies
Solubility	Slightly soluble in water ,very slightly soluble in methanol, practically insoluble in ethanol	Complies
Identification	A.The infrared absorption spectrum as the same as <i>Oxaliplatin CRS</i>	A.Complies
	B.Test for specific optical rotation	B.Complies
Apearance of solution	The solution is clear and colourless	Complies
Acidity	Not more than 0.6ml of 0.01M NaOH is required to change the colour of the indicator to pink	Complies
Specific optical rotation	+74.5°~+78.0°	+75.1°
Related substances	ImpurityA:NMT0.1% ImpurityB: NMT0.1% ImpurityC: NMT0.1% Any other impurity:NMT0.1% Total of other impurities: NMT0.1%(include impurity C) Total of impurities: NMT0.3%	ImpurityA 0.02% ImpurityB:0.02% ImpurityC: 0.002%: 0.004% 0.006% 0.060%
Impurity D	NMT0.1%	N.D
Residual solvents	Ethanol<5000ppm	Complies
	Aether<5000ppm	Complies
Silver	NMT5ppm	0.25ppm
Loss on drying	NMT0.5%	0.16%
Assay	98~102% (dried substance)	99.5%
Bacterial endotoxins	<1.0IU/mg	Complies

Conclusion: It complies with the EP7.2 Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F