



Certificate of analysis

Productname:Epirubicin HCl

Cas number:56390-09-1

Molecular Formula: C₂₇H₂₉N₀O₁₁.ClH

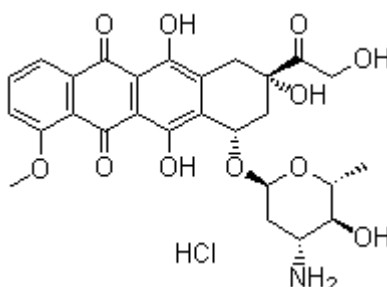
Molecular Weight: 579.98

Date of production:May. 25, 2018

Bacth NO:20180525

Exp Date: May. 24, 2020

Chemical structure:



Items	Specifications	Results
Appearance	orange red crystalline powder	Conforms
Identification	A: Infrared absorption (197M)	Conforms
	B: The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	
	C: IDENTIFICATION TESTS—GENERAL,Chloride, (191)	
Solubility	Soluble in water and in methanol, slightly soluble in anhydrous ethanol, practically insoluble in acetone	Conforms
pH	4.0—5.5	5.0
Acetone	≤1.5%	0.8%
Related Substance	Impurity A ≤1.0% Impurity C ≤1.0% Any other impurity ≤0.5% Total impurity ≤2.0%	Conforms
Bacterial Endotoxins	≤2.2 IU/mg	Conforms
Water	≤4.0%	0.93%
Assay (HPLC)	97.0%—102.0%	99.5%

Conclusion: It complies with the BP2013 Standard.

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F