



Certificate of analysis

Product name: **Daunorubicin Hydrochloride**

Cas number: 23541-50-6

Molecular Formula: $C_{27}H_{29}NO_{10} \cdot HCl$

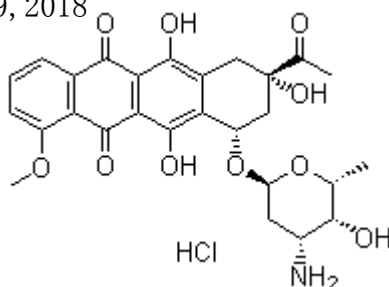
Molecular Weight: 563.99

Date of production: July. 29, 2018

Batch No: 20180729

Exp Date: July. 28, 2020

Chemical structure:



Items	Specifications	Results
Appearance	Orange-red or red crystalline powder; No visible evidence of contamination by foreign matter.	Conforms
Solubility	Lightly soluble in water or methanol, slightly soluble in ethanol(95%), practically insoluble in chloroform or acetone.	Conforms
Identification	A) IR spectrum corresponds to the IR spectrum of the reference standard B) The retention time of the main peak obtained with the assay preparation corresponds to that obtained with the standard preparation as directed in the assay	Conforms
PH	4.5~6.5	5.1
Water	≤3.0%	1.5%
Related substance		
Any other impurity	≤1.5%	1.16%
Total impurities	≤3.0%	2.5%
Residual solvents		
Both methanol & ethanol	≤0.2%	0.12%
Butyl alcohol	≤1.0%	0.5%
Acetone	≤0.5%	0.1%
Chloroform	≤0.6%	Conforms
Assay	842ug to 1030ug of $C_{27}H_{29}NO_{10}$ calculated on the anhydrous, solvent-free basis	935ug

Conclusion: It complies with USP36 standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F