



Certificate of analysis

Product name: **Doxorubicin Hydrochloride**

Cas number: 25316-40-9

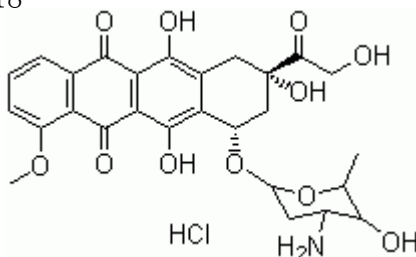
Molecular Formula: $C_{27}H_{29}NO_{11} \cdot HCl$

Molecular Weight: 579.99

Date of production: June. 22, 2018

Batch NO: 20180622

Exp Date: June. 21, 2020



Chemical structure:

Items	Specifications	Results
Appearance	Orange red or red crystalline powder; No visible evidence of contamination by foreign matter	Conforms
Identification A	IR spectrum corresponds to the IR spectrum of the reference standard	Conforms
Identification B	The retention time of the doxorubicin peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay	Conforms
Solubility	Soluble in water and methanol; slightly soluble in ethanol; practically insoluble in acetone	198.3-199.5°C
PH	4.0 to 5.5	4.9
Water	≤4.0%	2.1%
Related substances	Impurity A (Doxorubicinone) ≤0.5%	0.23%
	Any other unknown Impurity ≤0.2%	0.17%
	Total unknown Impurities ≤0.5%	0.37%
	Total Impurities ≤2.0%	0.6%
Assay (PHLC)	98.0%-102.0%	98.8%
Residual solvents	Acetone ≤0.5%	0.34%
	Acetone+Ethanol ≤2.5%	1.6%
	methanol ≤0.3%	0.07%
	Dichloromethane ≤0.06%	Not detected

Conclusion: It complies with the USP38 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F