

Beijing Yibai Biotechnology Co., Ltd

北京屹柏生物科技有限公司

Phone: 0086-010-60404860 Email: sales@yibaibiotech.comWebsite: www.yibaichem.com**检验报告书****CERTIFICATE OF ANALYSIS**

Product Name: Doxorubicin Hydrochloride		CAS No.:25316-40-9
Batch No.: QYB20180415		Quantity:562g
Date of Production : Apr., 15, 2018		Date of Testing: Apr.,17, 2018
Retest Date : Apr., 2020		Test according to: USP
ITEMS	STANDARDS	RESULTS
Appearance	Orange-red or red crystalline powder; No visible evidence of contamination by foreign matter	Complies
Solubility	Soluble in water and methanol; slightly soluble in ethanol; practically insoluble in acetone.	Complies
Identification	A: IR spectrum corresponds to the IR spectrum of the reference standard	Complies
	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.	Complies
pH	4.0 to 5.5	4.9
Water	Not More Than 4.0%	2.1%
Related Substances	Impurity A (Doxorubicinone) $\leq 0.5\%$	0.23%
	Any Other unknown Impurity $\leq 0.2\%$	0.17%
	Total unknown Impurities $\leq 0.5\%$	0.37%
	Total Impurities $\leq 2.0\%$	0.6%
Residual Solvents	Acetone $\leq 0.5\%$	0.34%
	Acetone +Ethanol $\leq 2.5\%$	1.6%
	methanol $\leq 0.3\%$	0.07%
	Dichloromethane $\leq 0.06\%$	Not Detected
Assay	98.0% ~ 102.0%	99.2%
Conclusion: The results conform to the standard of USP34.		