

Certificate of Analysis

Product Name	Doxorubicin HCL	CAS No.	25316-40-9
Batch No.	KN21121801	Mfg. Date	2021.12.18
Batch Qty.	1350g	Testing Date	2021.12.18
Quality Standard	USP41	Exp. Date	2023.12.17

Items	Specifications	Results
Appearance	Orange-red crystalline powder	Complies
Solubility	Soluble in water, in isotonic sodium chloride solution and in methanol. Practically insoluble in chloroform, in ether and in other organic solvents	Complies
Identification	The retention time in the chromatogram should correspond to that of the R.S.	Complies
Crystallinity	Meets the requirement	Complies
pH	4.0—5.5	5.1
Residual solvents		
Acetone and Ethanol	≤2.5%	0.32%
Acetone	≤0.5%	0.43%
Methanol	≤0.3%	Not detected
Dichloromethane	≤0.06%	Not detected
Loss on drying	≤40%	1.2%
Related substances		
Doxorubicinone	≤0.5%	0.07%
Daunorubicin	≤0.5%	Not detected
Epirubicin HCl	≤0.5%	Not detected
Any other impurity	≤0.5%	0.12%
Total impurities	≤2.0%	0.15%
Bacterial Edotoxins	≤2.2IU/mg	Complies
Assay (HPLC)	98.0%~102.0%	99.1
Conclusion:	The product complies with USP41	

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