杭州东瑞医药科技有限公司
HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.

CERTIFICATE OF ANALYSIS

Doxorubicin HCl

Batch No.: DR20140119	**Quantity :**10g
CAS No: 25316-40-9	**Standard :**USP34
Manufacture Date: 2014.01.19	**Expiry Date:** 2016.01.18

TESTS:

Items	Specification	Results
Characters	Orange-red crystalline powder.	Conforms
Solubility	Soluble in water, in isotonic sodium chloride solution and in methanol. Practically insoluble in chloroform, in ether and in other organic solvents	Conforms
Identification	The retention time of Doxorubicin peak in the chromatogram of Assay preparation corresponds to that in the standard preparation as obtained in Assay	Conforms
Crystallinity	Meets the requirements of USP	Conforms
pH	4.0—5.5	4.6
Residual solvents		
Acetone and alcohol	≤2.5%	0.23%
Acetone	≤0.5%	0.12%
Methanol	≤500ppm	ND
Dichloromethane	≤500ppm	ND
n-Propanol	≤5000ppm	ND
1,4-Dioxane	≤250ppm	ND
Chloroform	≤60ppm	ND
Water	≤4.0%	0.6%
Related substances		
Doxorubicinone	≤0.5%	0.07%
Daunorubicin	≤0.5%	ND
Epirubicin HCl	≤0.5%	ND
Any other impurity	≤0.5%	0.13%
Total impurities	≤2.0%	0.18%
Assay(by HPLC)	98.0%—102.0% on anhydrous and solvent free basis	99.4%
Storage: In an airtight container, protected from light, Store in a dry place below 25℃		
Conclusion: The results conform with the USP34 .		

杭州东瑞医药科技有限公司 Hangzhou Dawn Ray Pharmaceutical Co.,Ltd. 质检专用章 QUALITY CONTROL

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