Hangzhou Huarong Pharmaceutical Co., Ltd.

ADD: Room1101, Hakim International Building, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373 Website: www.huarongpharm.com

Product name	Daunorubicin Hydrochloride for Injection		
Batch No.	037210301	Batch size	18939 bottles
Manufacturing date	Mar.14, 2021	Expiry Date	Feb., 2023
Test items	**Acceptance criteria**		**Test results**
Appearance	A red loose mass or powder		Conforms
Identification	Liquid chromatogram: In the Assay, the retention time of the principal peak in the chromatogram obtained with the test solution is identical with that of the principal peak in the chromatogram obtained with the reference solution.		Conforms
	Chemical reaction: A white curd-like precipitate is formed.		Conforms
Related compounds	Any other single impurity: NMT 2.0% Total impurities: NMT 3.0%		0.56% 1.4%
Content uniformity	Should be conformed		A+2.2S=1.1＜15.0
Acidity	PH should be 4.5~6.5		5.1
Water	NMT3.0%		0.64%
Insoluble particles	Particles equal and greater than 10 μm is not more than 6000 per bottle. Particles equal and greater than 25 μm is not more than 600 per bottle.		7 per bottle 0 per bottle
Visible particles	Should be conformed		Conforms
Depressor substance:	Should be conformed		Conforms
Bacterial endotoxin	The amount of endotoxin per 1mg daunorubicin should be less than 4.3EU.		＜4.3EU/mg
Sterility	Should be conformed		Conforms
Assay:	Should be 90.0% ~110.0%		99.3%
Conclusion	The results conform to standards.		

HANGZHOU HUARONG PHARMACEUTICAL CO., LTD. 杭州华嵘医药有限公司 QC

*Means the document is under process
Product under patent is for R&D purpose.