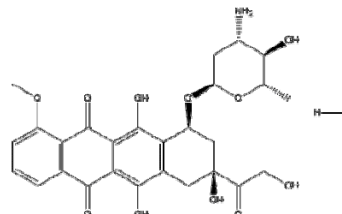


Certificate Of Analysis

Name: Epirubicin hydrochloride
CAS No.: 56390-09-1
Cat No.: A857961
Molecular Formula: C₂₇H₂₉NO₁₁.HCl
Molecular Weight: 579.98
Batch No.: E25122019
Mfg.Date: 2019.12.25
Exp.Date: 2021.12.24



Items	Specifications		Results
Appearance	Orange-red powder		Conforms
Identification	A:IR Identification	The infrared absorption spectrum corresponds to that of epirubicin hydrochloride CRS	Conforms
	B: HPLC Identification	The retention time of the epirubicin peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Conforms
	C: Chloride Identification	Chloride Identification exhibits positive	Conforms
PH	4.0~5.5		5.0
Related Substances	Doxorubicinone≤1.0%		0.08%
	Daunorubicinone≤0.5%		Conforms
	Doxorubicin≤1.0%		0.40%
	Daunorubicin≤0.5%		Conforms

	Dihydrodaunorubicin \leq 0.5%	Conforms
	Epidaunorubicin \leq 1.0%	Conforms
	Epidaunorubicin \leq 1.0%	Conforms
	Any other impurity \leq 0.5%	0.13%
	Total impurities \leq 3.0%	0.66%
Residual Solvents	Methanol \leq 3000ppm	232ppm
	Ethanol \leq 5000ppm	4924ppm
	Acetone \leq 15000ppm	149ppm
	Dichloromethane \leq 600ppm	Conforms
	Dioxane \leq 380ppm	Conforms
	Chloroform \leq 60ppm	Conforms
Water	\leq 4.0%	2.7%
Bacterial endotoxins	<1.1 Units/mg	<1.1 Units/mg
Assay	97.0%-102%	98.6%
Conclusion	The product conforms to USP39.	

Storage condition: Store in a tightly closed container in a cool and dry place.

Checker:

 *If you have any comments and suggestions, please contact us by sales@amadischem.com

*For R&D use only