



Wuhan Biocause Pharmaceutical Development Co., Ltd

武汉百科药物开发有限公司

Certificate of Analysis

质检专用章

No.:F-312-16033

Product: Milrinone

Test Standard: USP39

Batch Number: 312-161106

Quantity: 2199.3g

Date of Manufacture: 2016-12-06

Date of Test: 2016-12-19

Retest date: 2018-12-05

Items	Specifications	Results
Appearance	White to tan crystalline powder	Off-white crystalline powder
<u>Identification</u>	A. Sample IR spectrum corresponds with that of the standard.	Conforms
A. IR Spectrum	B. The RT of the major peak of the Test solution corresponds to that of the Standard solution, as obtained in the Assay.	Conforms
B. HPLC		
Water	Not more than 2.0%	0.30%
Residue on Ignition	Not more than 0.2%	0.02%
Heavy Metals	Not more than 0.002%	<0.002%
Organic Impurities	1,6-dihydro-2-methyl-6-oxo-(3,4'-bipyridine)-5-carboxamide (Impurity A): NMT 0.1%	0.06%
	Any individual impurity: NMT 0.10%	0.01%
	Total impurities: NMT 1.0%	0.09%
Residual Solvents	Methanol: NMT 1000ppm	ND
	Ethanol: NMT 1000ppm	ND
	Dichloromethane: NMT 300ppm	ND
Assay (by HPLC)	98.0~102.0% (calculated on the anhydrous basis)	99.6%
Conclusion: The product meets USP39 specifications.		

QC Supervisor: 2176

Checked by: 2017.1.4

Analyst(s): 2017.1.4

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