

CERTIFICATE OF ANALYSIS

Product name	Milrinone lactate	
Batch NO:	JZ20180706	
Mfg.Date:	July 2018	
Analysis Date:	6 July 2018	
Testing Items	Specifications	Results
Appearance	A white or light yellow crystalline powder,hardly soluble in water and ethanol,more or less soluble in methanol and freely soluble in sparse hydrochloric acid.	complied
Identifications	A:Infrared absorption,should conforms with the standard spectrum B:The retention time of the major peak in the chromatogram of the test solution.corresponds to that in the chromatogram of the standard spectrum	complied
Water	≤1.0%	≤0.25%
Residue on Ignition	≤0.2%	≤0.05%
Heavy Metals	≤20PPM	<10PPM
Related Substances	Single impurity:≤0.3% Total impurity:≤1.0%	0.13% 0.17%
Purity(by HPLC)	≥98.5%	99.2%
Organic volatile impurities	Should meets the requirements.	Complied
Residual Solvents	Ethanol:≤1000PPM Ether:≤100PPM DMF:≤250PPM Methanol:≤1000PPM Dichloromethane:≤300PPM	300PPM N.D. N.D 110PPM