



Certificate of analysis

Productname : Argatroban

Cas number : 141396-28-3

Molecular Formula : C₂₃H₃₆N₆O₅·H₂O

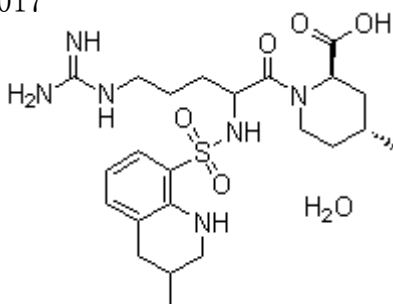
Molecular Weight : 526.65

Date of production : Mar. 25, 2017

Batch NO : 20170325

Exp Date : Mar. 24, 2019

Chemical structure :



Items	Specifications	Results
Appearance	White crystal or off-white crystal powder	Off-white crystal powder
Identification	IR: IR spectrum of test sample should conform to that of Argatroban CRS	Conform
	UV: It should have the same maximum absorption as Argatroban CRS	Conform
Specific rotation	+175.0 ° ~ +185.0 °	175.1 °
Related substance I	For each impurity NMT 0.10%	0.01%
	Total impurities NMT 0.50%	0.01%
Residual solvents	Methanol NMT 3000ppm	ND
	Dichloromethane NMT 600ppm	ND
	n-heptane NMT 5000ppm	ND
	Ethyl acetate 5000ppm	ND
	Tert-butyl methyl ether NMT 5000ppm	ND
Heavy metals	NMT 10ppm	Conform
Residue on ignition	NMT 0.10%	0.05%
Water (KF)	3.0 ~ 4.5%	3.6%
Ratio of Isomers	Ab / (Aa + Ab) should be 0.3 ~ 0.4	0.35
Assay (HPLC)	98.5% ~ 101.0%	99.9%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F