



武汉泽山成生物医药有限公司
Wuhan ZeShanCheng Biomedical Technology Co., Ltd.

Certificate Of Analysis

Product Name	ticagrelor		
Batch No	20181008	Batch Size	60kg
Manufacture Date:	20181008	Expire Date	20201008
CAS No	274693-27-5	Ref. standard	In-house standard

TEST	Specifications	Test Results
Appearance	White to off white solid powder	Conform
Identification	IR	Conform
	HPLC	Conform
Loss on drying	≤0.5%	0.14%
Optical rotation	-50.0° - -60.0°	-53.0°
Residue on Ignition	≤0.1	0.07%
Isomers	TGD1≤0.15%	Undetected
	TGD2≤0.15%	Undetected
	TGE≤0.15%	Undetected
	TG-16≤0.15%	Undetected
Related substance	De-ethoxyl of TG≤0.15%	0.01%
	Any Single impurity: ≤0.1%	0.04%
	Total impurities: ≤1.0%	0.10%
residual Solvents	Ethyl ether <5000ppm	Undetected
	Acetone<5000ppm	Undetected
	Dichloromethane <600ppm	Undetected
	Ethyl acetate <5000ppm	73ppm
	triethylamine <320ppm	Undetected
	toluene<890ppm	Undetected
	Tetrahydrofuran <720ppm	Undetected
	Methanol<3000ppm	Undetected
	Ethanol<5000ppm	Undetected
	Acetonitrile<410ppm	Undetected
Assay	N-hexane<290ppm	Undetected
	N-methyl pyrrolidone<530ppm	Undetected
	99~102%	100.5%



质检负责人: Albert Lulu
CHIEF OF Q.C. DEPT

分析: Wang
ANALYS02