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四川青益纯医药科技有限公司
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CERTIFICATE OF ANALYSIS

Product Name	Ticagrelor	CAS No.	274693-27-5
Batch No.	P020661217A	Mfg. Date	Jun. 14, 2017
Quantity	25kg	Retest Date	Jun. 13, 2019
Packing	25kg/Drum	Report Date	Jun. 18, 2017
Specification	Enterprise Standard		

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white powder	White powder
Solubility	Freely soluble in methanol, dimethyl sulfoxide and N,N-dimethyl formamide, dissolve in ethanol, slightly soluble in acetonitrile and ethyl acetate, practically insoluble in water, heptane, 0.1 M hydrochloric acid and 0.1 M NaOH.	Complies
Absorption coefficient	290 to 320	298.2
Specific optical rotation	-70.0° to -60.0°	-65.0°
Melting range	136.0°C ~139.0°C	138.0° ~138.5°C
Identification	1) Chemical identification: Positive result. 2) UV: It shows a maximum absorption at the wavelength of 220nm and 258nm, and it shows a minimum absorption at 242nm and 268nm. 3) IR: Correspond to the IR spectrum of reference standard.	1) Positive 2) Complies 3) Complies
Loss on drying	≤0.5%	0.05%
Residue on Ignition	≤0.1%	0.02%
Heavy Metals	≤20ppm	Complies
Related Substances		
-POZ1, POZ2, POZ3, POZ4, POZ5, POZ7, POZ8, POZ9, POZ10, POZ11	≤0.1%	N.D
-POZ6	≤0.1%	N.D
-POZ12	≤0.1%	N.D
-Any other unspecified impurity	≤0.1%	0.06%
-Sum of unspecified impurities	≤1.0%	0.06%



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Residual Solvents		
Methanol	≤3000ppm	Complies
Ethyl Acetate	≤5000ppm	Complies
Acetone	≤5000ppm	Complies
Assay(on dried basis)	98.0%~102.0%	99.56%
Conclusion	The product conforms to Enterprise Standard.	
Remarks	N/A	

Analyst:

QC Manager:

QA: