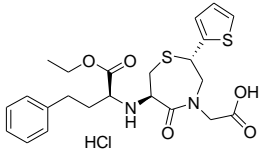


分 析 报 告

Certification of Analysis

Product Name	Temocapril hydrochloride		
CAS No	110221-44-8	MFG.DATE	2019-09-06
Batch number	SYBC20190906	TEST DATE	2019-09-06
Quantity	6.0kg	Expiry Date	2021-09-05
Specification	25g/Drum	Standard	Enterprise standard
 Structure: MF: C ₂₃ H ₂₈ N ₂ O ₅ S ₂ MW: 513.07			

RESULT OF INSPECTION

Items	Specification	Results
Appearance	Off-white to white powder	White powder
Identification	¹ H NMR spectrum of sample corresponds to that of standard preparation	Conforms
	The retention time of the major peak in the chromatogram of sample corresponds to that in the chromatogram of standard preparation	Conforms
specific rotation[α] (C=1 DMF)	+46.0° ~ +50.0°	+47.5.0°
water	≤0.5%	0.1%
Relative Substance by HPLC	Impurity A: ≤0.15%	0.03%
	Largest single impurity: ≤0.1%	0.08%
	Total Impurities: ≤0.5%	0.39%
Purity (HPLC)	≥99.0%	99.65%
Residual solvents(GC)	Ethanol: ≤5000ppm	<100ppm
	Acetonitrile: ≤410ppm	<100ppm
	Ethyl acetate: ≤5000ppm	<100ppm
	Dichloromethane: ≤600ppm	<100ppm
	Isopropyl ether: ≤500ppm	<100ppm
Conclusion	The product conforms to monohydrate releasestandards.	
Storage condition	Store in a tightly closed container in a cool and dry place	

QC: Amy wang

Checker: Susan Xu

Approved: Li hong