

## CERTIFICATE OF ANALYSIS

Product Name	Sacubitril Valsartan Sodium		
Batch No.	2021121301	CAS No.	936623-90-4
Manufacturing Date	December 13, 2021	Expiry Date TO	December 12, 2023
Report Date	January 7, 2022	Quality Standard	In-house Specification
Analytical results			
Items	Specifications	Results	
Appearance	White to almost white powder	white powder	
Identification	IR: spectrum should correspond to reference substance	Conform	
	UV: spectrum should correspond to reference substance	Conform	
	XRPD: spectrum should correspond to reference substance	Conform	
Water	4.0%~ 5.9%	4.6%	
Heavy Metals	≤10ppm	Conform	
Stereoisomers	SCB (S,S)≤0.15%	N.D.	
	SCB (S,R)≤0.15%	N.D.	
	SCB (R,R)≤0.15%	N.D.	
	VST impurity A≤0.5%	N.D.	
Residual Solvents	Acetone≤5000ppm	N.D.	
	Ethanol≤5000ppm	N.D.	
	Isopropyl acetate≤5000ppm	N.D.	
	Isopropanol≤5000ppm	N.D.	
Related substances	SCB impurity A≤0.1%	N.D.	
	SCB impurity B≤0.1%	0.01%	
	SCB impurity C≤0.1%	0.01%	
	SCB impurity D≤0.1%	N.D.	
	SCB impurity E≤0.1%	N.D.	
	Other single impurity≤0.1%	0.01%	
	Total impurities≤1.0%	0.03%	
Sodium	7.17%~7.93%	7.54%	
Assay	Sacubitril :43.5%~46.5%	45.10%	
	Valsartan:46.2%~49.2%	47.50%	
	Sacubitril Valsartan Sodium:98.0%~101.5%	100.10%	
Conclusion	Complies to In-house specification.		

Inspector: Carlifor Wu

Verifier: Jack He