



Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

CERTIFICATE OF ANALYSIS

Product : Sacubitril Valsartan Sodium
 Quantity : 106.2Kg
 Batch NO. : LCZ696-702-221202
 Test Basis : SOP-QC-API-065-4/SOP-QC-API-067-1

Manufacturing Date : Dec. 05, 2022
 Retest Date : Dec. 05, 2024

Tests	Specifications	Results
Appearance	White or off-white powder	White power
Identification	A. Retention Time: Similar to Reference Substance	Complies
	B. IR: Similar to Reference Substance	Complies
	C. The X-ray diffraction patterns of this product have diffraction peaks at 2 theta as follows: $4.3^{\circ} \pm 0.2^{\circ}$ 、 $12.6^{\circ} \pm 0.2^{\circ}$ 、 $17.0^{\circ} \pm 0.2^{\circ}$	Complies
Water	4.0%~5.9%	4.8%
Related Substance	SX-9-D \leq 0.15%	Undetected
	SX-11-B \leq 0.15%	Undetected
	Single impurity \leq 0.10%	Undetected
	Total impurities \leq 1.0%	Undetected
Isomer	SX-11-A \leq 0.50%	Undetected
	SX-9-C \leq 0.15%	Undetected
	SX-9-A \leq 0.15%	Undetected
	SX-9-B \leq 0.15%	Undetected
Residual Solvents	Ethanol \leq 5000ppm	Undetected
	Acetone \leq 5000ppm	21ppm
	Isopropyl alcohol \leq 5000ppm	Undetected
	Dichloromethane \leq 600ppm	Undetected
	Methyl t-butyl ether \leq 5000ppm	Undetected
	Ethyl acetate \leq 5000ppm	Undetected
Residual Solvents	Isopropyl acetate \leq 5000ppm	44ppm
Assay	SX-11: 49.8%~52.4% (Based on anhydrous and sodium-free)	51.6%
	SX-10: 47.1%~49.6% (Based on anhydrous and sodium-	48.6%
Na	6.5%~8.5% (anhydrous substance)	7.6%
Pb	\leq 0.5ppm	0.2449ppm
Ca	\leq 1000ppm	66ppm
PSD	D90 \leq 20 μ m	19.182 μ m

The results above meet all requirements under **Sacubitril Valsartan Sodium In-House Standard**.

