

Beijing Yibai Biotechnology Co., Ltd

北京屹柏生物科技有限公司

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Valsartan/Sacubitril CAS No.: 936623-90-4		
Batch No.: QYB20180528	Quantity:120kg	
Date of Production : May., 28, 2018	Date of Testing: May.,30 2018	
Retest Date : May., 2020	Test according to: In-house	
ITEMS	STANDARDS	RESULTS
Appearance	White to off-White Powder	Off-white powder
Identification	IR,UV,XRD	Complies
Water(K.F)	4.0%-5.9%	5.1%
Related Substances(HPLC)	Unspecified impurity NMT 0.1% Total impurities NMT 1.5%	0.02% 0.02%
Heavy metals	≤10ppm	Complies
Stereoisomers(HPLC)	≤0.5%	ND
Residue Solvents	Acetone NMT 5000ppm Ethanol NMT 5000ppm Isopropyl acetate NMT 5000ppm Isopropanol NMT 5000ppm	ND 42ppm ND ND
Assay(calclueted as free acid on an anhydrous and solvent free basis)	Valsartan 49.8%~52.4% AHU377 47.1%~49.6% LCZ696 98.0%~101.5%	51.2% 48.8% 98.5%
Sodium	7.17%-7.93%	7.2%
Conclusion	Complies with specification.	