Lot: 0030317

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CERTIFICATE OF ANALYSIS

Product name	Captopril		
Batch no.	5102-16-059	Batch Size	214.60Kg
Batch Type	Commercial	Report Date	2016-12-02
Retest Date	2019-10	Storage Condition	Preserved in a well-closed container
Manufacture Date	2016-11-14	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024 China.
Reference	R1-CEP 1997-023-Rev 07		
Test Items	Specifications		Results
Appearance	White or almost white crystalline powder		White crystalline powder
Solubility	Soluble in water, freely soluble in methanol and in methylene chloride, it dissolves in dilute solutions of alkali hydroxides.		Conforms
Identification	Specific optical rotation: -127～-132°		-131°
	Infrared absorption spectrum concordant with spectrum obtained with captopril CRS.		Conforms
Appearance of Solution S	Clear and colorless		Clear and colorless
pH	2.0～2.6		2.4
Related substances (HPLC)	Impurity A ≤ 1.0%		0.07%
	Impurity C ≤ 0.15%		N.D(LOD=0.01%)
	Impurity E ≤ 0.15%		N.D(LOD=0.02%)
	Impurity J ≤ 0.20%		<LOD(LOD=0.006%)
	Any unspecified impurity ≤ 0.10%		<LOQ(LOQ=0.05%)
	Total impurities ≤ 1.2%		0.07%
Related Substances (GC)	Impurity F ≤ 0.2%		0.09%
Heavy Metals	≤20ppm		<20ppm
Loss on Drying	≤1.0%		<0.1%
Sulphated Ash	≤0.2%		0.1%
Zinc（AAS）	≤20ppm		<LOD(LOD=0.4ppm)
Assay (Titration)	98.0～101.5% (calculated on dried basis)		100.6%
2-Amino-1-Butanol	≤0.1%		<0.1%
Conclusion	Complies with R1-CEP 1997-023-Rev 07		

Signature : kefeng (QC manager) Issued Date: 2016.12.02

Signature : Wujing lan (QA manager) Issued Date: 2016.12.06