



浙江华海药业股份有限公司

HUHHAI ZHEJIANG HUHHAI PHARMACEUTICAL CO.,LTD.

lot: 0150420

中国 浙江 临海市汛桥
XUNQIAO, LINHAI
ZHEJIANG 317024, CHINA.
Tel: +86(576)85010288
Fax: +86(576)85991062

Email: sales@huahai pharm.com
http://www.huahai pharm.com

CERTIFICATE OF ANALYSIS

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Product name	Captopril		
Batch No.	5102-19-008	Batch Size	215.14kg
Batch Type	Commercial	Report Date	2019-08-22
Retest Date	2022-06	Storage Condition	Preserved in a well-closed container
Manufacture Date	2019-07-23	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024 China.
Reference	R1-CEP 1997-023-Rev 09		
Test Items	Specifications	Results	
Appearance	White or almost white crystalline powder	White crystalline powder	
Identification	Specific optical rotation: -127~-132°	-130°	
	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%	<LOD(LOD=0.01%)	
	Impurity E ≤ 0.15%	<LOD(LOD=0.02%)	
	Impurity J ≤ 0.20%	<LOQ(LOQ=0.02%)	
	Any unspecified impurity ≤ 0.10%	<LOD(LOD=0.01%)	
	Total impurities ≤ 1.2%	0.07%	
Related Substances (GC)	Impurity F ≤ 0.2%	0.05%	
Loss on Drying	≤1.0%	0.1%	
Sulphated Ash	≤0.2%	<0.1%	
Elemental impurity (Zinc ICP-MS)	≤20ppm	<LOD(LOD=2ppm)	
Assay (Titration)	98.0~101.5% (calculated on dried basis)	100.7%	
Conclusion	Complies with R1-CEP 1997-023-Rev 09		

Signature: Zhuang (QC manager)

Issued Date: 2019.08.22

Signature: Wujinglan (QA manager)

Issued Date: 2019.08.22