

Lot: 0210521



浙江华海药业股份有限公司

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CERTIFICATE OF ANALYSIS

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Product name	Captopril		
Batch No.	5102-20-018	Batch Size	300.36kg
Batch Type	Commercial	Report Date	2020-12-26
Retest Date	2024-04	Storage Condition	Preserved in a well-closed container
Manufacture Date	2020-05-07	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024 China
Reference	R1-CEP 1997-023-Rev 10		
Test Items	Specifications	Results	
Appearance	White or almost white crystalline powder	White crystalline powder	
Identification	Specific optical rotation: -127~-132°	-129°	
	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	
	Impurity E ≤ 0.15%	N.D	
	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 (HPLC)	Impurity F ≤ 0.2%	<LOD(LOD=0.02%)	
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)	100.5%	
Conclusion	Complies with R1-CEP 1997-023-Rev 10		

Signature: *Lu Caichong* (QC manager)

Issued Date: *2020.12.26*

Signature: *Wu Jinglan* (QA manager)

Issued Date: *2020.12.29*

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