



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.	5102-22-026	Batch Size	300.36kg
Batch Type	Commercial	Report Date	2022-05-21
Retest Date	2026-05-08	Storage Condition	Preserved in a well-closed container
Manufacture Date	2022-05-09	Manufacture Site	Xunqiao, Linhai, Zhejiang, 317024, China.
Reference	R1-CEP 1997-023-Rev 10		
Test	Specification		Results
Appearance	White or almost white crystalline powder		White crystalline powder
Identification	Specific optical rotation: -127~-132°		-129°
Identification	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
Loss on Drying	≤1.0%		0.1%
Sulphated Ash	≤0.2%		<0.1%
Elemental impurity(ICP-MS)	≤20ppm		<LOD
Zinc			
Related substances(HPLC)	≤1.0%		0.11%
Impurity A			
Related substances(HPLC)	≤0.15%		<LOD
Impurity C			
Related substances(HPLC)	≤0.15%		N.D
Impurity E			
Related substances(HPLC)	≤0.20%		<LOQ
Impurity J			
Related substances(HPLC)	≤0.10%		<LOD
Any unspecified impurity			
Related substances(HPLC)	≤1.2%		0.11%
Total impurities			
Related substances(HPLC)	≤0.2%		N.D
Impurity F			
Assay(Titration)	98.0~101.5% (calculated on dried basis)		100.3%
Conclusion	Complies with R1-CEP 1997-023-Rev 10		

Signature: ZHUXING

(QC manager)

Issued Date: 2022-05-21

Signature: WUJINGLAN

(QA manager)

Issued Date: 2022-05-21

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