

METAPHARMACEUTICAL

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浙江华海药业股份有限公司

HUNHAI ZHEJIANG HUNHAI PHARMACEUTICAL CO., LTD.

Certificate of Analysis

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Product Name	Captopril		
Batch No.	5102-24-004	Batch Size	321.575kg
Batch Type	Commercial	Report Date	2024-03-15
Re-test Date	2028-03-09	Storage Condition	Preserved in a well-closed container
Manufacture Date	2024-03-10	Manufacture Site	Xunqiao, Linhai, Zhejiang, 317024, China.
Reference	RI-CEP 1997-023-Rev 10		
Test	Specification		Results
Appearance	White or almost white crystalline powder		White crystalline powder
Identification	Specific optical rotation: $-127^{\circ} \sim -132^{\circ}$		-130°
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		2.3
Loss on Drying	$\leq 1.0\%$		0.1%
Sulphated Ash	$\leq 0.2\%$		$< 0.1\%$
Elemental impurity (ICP-MS) Zinc	$\leq 20\text{ppm}$		$< \text{LOD}$
Related substances (HPLC) Impurity A	$\leq 1.0\%$		0.11%
Related substances (HPLC) Impurity C	$\leq 0.15\%$		N.D
Related substances (HPLC) Impurity E	$\leq 0.15\%$		N.D
Related substances (HPLC) Impurity J	$\leq 0.20\%$		$< \text{RL}$
Related substances (HPLC) Any unspecified impurity	$\leq 0.10\%$		$< \text{LOQ}$
Related substances (HPLC) Total impurities	$\leq 1.2\%$		0.11%
Related substances (HPLC) Impurity F	$\leq 0.2\%$		N.D
Assay (Titration)	98.0~101.5% (calculated on dried basis)		100.0%
Conclusion	Complies with RI-CEP 1997-023-Rev 10		

Signature: WANGXIANG (QC manager)

Issued Date: 2024-03-15

Signature: DENGMEIZHOU (QA manager)

Issued Date: 2024-03-15

Notes: COA was generated by LIMS with electronic signatures.

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