



HUHAI

浙江华海药业股份有限公司

ZHEJIANG HUHAIPHARMACEUTICAL CO., LTD.

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Certificate of Analysis

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Product Name	Captopril		
Batch No.	5102-20-028	Batch Size	300.42kg
Batch Type	Commercial	Report Date	2020-11-18
Retest Date	2024-10-30	Storage Condition	Preserved in a well-closed container
Manufacture Date	2020-10-31	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) Zinc	≤20ppm		<LOD
Related substances(HPLC) Impurity A	≤1.0%		0.22%
Related substances(HPLC) Impurity C	≤0.15%		<LOD
Related substances(HPLC) Impurity E	≤0.15%		N.D
Related substances(HPLC) Impurity J	≤0.20%		<LOQ
Related substances(HPLC) Any unspecified impurity	≤0.10%		<LOQ
Related substances(HPLC) Total impurities	≤1.2%		0.22%
Related substances(HPLC) Impurity F	≤0.2%		<LOD
Assay(Titration)	98.0~101.5% (calculated on dried basis)		99.9%
Conclusion	Complies with R1-CEP 1997-023-Rev 10		

Signature: ZHUXING (QC manager)

Issued Date: 2020-11-17

Signature: DENGMEIZHOU (QA manager)

Issued Date: 2020-11-18

Notes: COA was generated by LIMS with electronic signatures.

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Product Name	Captopril		
Batch No.	5102-20-029	Batch Size	300.40kg
Batch Type	Commercial	Report Date	2020-11-18
Retest Date	2024-10-31	Storage Condition	Preserved in a well-closed container
Manufacture Date	2020-11-01	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) Zinc	≤20ppm		<LOD
Related substances(HPLC) Impurity A	≤1.0%		0.12%
Related substances(HPLC) Impurity C	≤0.15%		<LOD
Related substances(HPLC) Impurity E	≤0.15%		N.D
Related substances(HPLC) Impurity J	≤0.20%		<LOQ
Related substances(HPLC) Any unspecified impurity	≤0.10%		<LOQ
Related substances(HPLC) Total impurities	≤1.2%		0.12%
Related substances(HPLC) Impurity F	≤0.2%		<LOD
Assay(Titration)	98.0~101.5% (calculated on dried basis)		100.0%
Conclusion	Complies with R1-CEP 1997-023-Rev 10		

Signature: ZHUXING (QC manager)

Signature: DENGMEIZHOU (QA manager)

Notes: COA was generated by LIMS with electronic signatures.

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Product Name	Captopril		
Batch No.	5102-20-030	Batch Size	300.38kg
Batch Type	Commercial	Report Date	2020-11-18
Retest Date	2024-11-01	Storage Condition	Preserved in a well-closed container
Manufacture Date	2020-11-02	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) Zinc	≤20ppm		<LOD
Related substances(HPLC) Impurity A	≤1.0%		0.19%
Related substances(HPLC) Impurity C	≤0.15%		<LOD
Related substances(HPLC) Impurity E	≤0.15%		N.D
Related substances(HPLC) Impurity J	≤0.20%		<LOQ
Related substances(HPLC) Any unspecified impurity	≤0.10%		<LOQ
Related substances(HPLC) Total impurities	≤1.2%		0.19%
Related substances(HPLC) Impurity F	≤0.2%		<LOQ
Assay(Titration)	98.0~101.5% (calculated on dried basis)		99.9%
Conclusion	Complies with R1-CEP 1997-023-Rev 10		

Signature: ZHUXING (QC manager)

Signature: DENGMEIZHOU (QA manager)

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