



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: $-127^{\circ}$ ~ $-132^{\circ}$                         |                   | $-129^{\circ}$                            |
| 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                                       | $\leq 1.0\%$                                                                       |                   | 0.1%                                      |
| Sulphated Ash                                        | $\leq 0.2\%$                                                                       |                   | $< 0.1\%$                                 |
| Elemental impurity(ICP-MS)<br>Zinc                   | $\leq 20\text{ppm}$                                                                |                   | $< \text{LOD}$                            |
| Related substances(HPLC)<br>Impurity A               | $\leq 1.0\%$                                                                       |                   | 0.11%                                     |
| Related substances(HPLC)<br>Impurity C               | $\leq 0.15\%$                                                                      |                   | $< \text{LOD}$                            |
| Related substances(HPLC)<br>Impurity E               | $\leq 0.15\%$                                                                      |                   | N.D                                       |
| Related substances(HPLC)<br>Impurity J               | $\leq 0.20\%$                                                                      |                   | $< \text{LOQ}$                            |
| Related substances(HPLC)<br>Any unspecified impurity | $\leq 0.10\%$                                                                      |                   | $< \text{LOD}$                            |
| Related substances(HPLC)<br>Total impurities         | $\leq 1.2\%$                                                                       |                   | 0.11%                                     |
| Related substances(HPLC)<br>Impurity F               | $\leq 0.2\%$                                                                       |                   | N.D                                       |
| 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

Notes: COA was generated by LIMS with electronic signatures. Release date: 2022.05.23

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