Agency for medicinal products and medical devices of the Republic of Slovenia

CERTIFICATE NUMBER: ***409-10/2019-5***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Slovenia confirms the following:
The manufacturer: ***ZHEJIANG HUAHAI PHARMACEUTICAL Co., Ltd.***
Site address: ***Xunqiao, Linhai, Zhejiang, 317024, China***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-10-24*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
Building F2				

Clarifying remarks (for public users)

The inspection was performed based on the request of the MIA holder KRKA, tovarna zdravil, d.d., Novo mesto, Šmarješka cesta 6, 8000 Novo mesto, Slovenija. The certificate is valid only for the manufacture of finished products from active ingredients, qualified by KRKA, tovarna zdravil, d.d.

2020-02-18

Name and signature of the authorised person of the Competent Authority of Slovenia

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Confidential
Agency for medicinal products and medical devices of the Republic of Slovenia
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