Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 27485 Insp GMP 27485/992430-0001[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : ZHEJIANG MEDICINE COMPANY LIMITED XINCHANG PHARMACEUTICAL FACTORY

Site address : ZHEJIANG MEDICINE COMPANY LIMITED XINCHANG PHARMACEUTICAL FACTORY, XINCHANG PHARMACEUTICAL FACTORY, 98 EAST XINCHANG DADAO ROAD, XINCHANG, CN-312 500, CHINA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 16 of The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 26/07/2021, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) 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

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Restrictions or Remarks

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. A risk-based site inspection programme remains in force. The inspection was of non-sterile finished dosage form tablets manufactured in Workshop 109 (part of building 2102). The approval to manufacture products includes approval for primary packaging of the product.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Workshop 109 (also referred to as Plant 109)				

20/12/2021	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP MHRA-GMDP MHRA-GMDP MHRA-GMDP