Medicines and Healthcare products Regulatory Agency

Report No : UK GMP 27485 Insp GMP 27485/992430-0002

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

- Regulation 331 of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following:
The Manufacturer: ZHEJIANG MEDICINES COMPANY LTD

Site address:

ZHEJIANG MEDICINES COMPANY LTD, XINCHANG PHARMACEUTICAL FACTORY, 98 EAST XINCHANG DADAO ROAD, XINCHANG, ZHEJIANG PROVINCE, CN-312 500, CHINA

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***18/11/2024*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17(3) of the Human Medicines Regulations 2012 (as amended)

Part 2

Human Medicinal Products
1. MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.2] Lyophilisates [1.1.1.4] Small volume liquids

Restrictions or remarks: The scope of this statement of non-compliance is limited to the sterile medicinal products, manufactured within workshop 117, in building 3208.

Part 3

MHRA-GMDP MHRA

Nature of non-compliance :
The inspection identified 2 critical findings; the first regarding sterility assurance and contamination controls, and the second regarding the validity and suitability of reported data. 1. The controls in place were such that they posed a significant risk of contaminating sterile medicinal products. 2. Reported data could not be relied upon and resulted in (but was not limited to) contaminated equipment being used with potential to contaminate the sterile products being manufactured.

Reason:
Not applicable – The site is not currently authorised to manufacture sterile medicinal products. The critical findings are attributed to the initial site inspection, based on an application made for the site to manufacture sterile medicinal products. The marketing authorisation applicant, post inspection, has withdrawn the application.

Withdrawal of current valid GMP certificates:
Not applicable – The site is not currently authorised to manufacture sterile medicinal products. The critical findings are attributed to the initial site inspection, based on an application made for the site to manufacture sterile medicinal products. The marketing authorisation applicant, post inspection, has withdrawn the application.

Marketing authorisation action :
Not applicable – The marketing authorisation applicant, post inspection, has withdrawn the application.

Recall of batches:
Not applicable – no batches have been released. Site is not authorised to manufacture sterile medicinal products.

02/05/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential

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