Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 39387 Insp GMP 39387/2495799-0003[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 : QILU TIANHE PHARMACEUTICAL COMPANY LIMITED

Site address : QILU TIANHE PHARMACEUTICAL COMPANY LIMITED, 849 DONGJIA TOWN, LICHENG DISTRICT, JINAN, CN-250105, 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 17/11/2014, 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

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.2] Lyophilisates

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other
sterile APIs and non-sterile APIs

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Restrictions or Remarks

Following a risk-based review of GMP compliance information conducted on 9th November 2017, the validity period of this certificate is extended to 9th November 2018.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
This inspection only covered the sterile manufacture and support activities such as QC for products manufactured in Workshops 4 (lines 1 and 3), 7(lines 2 and 3. Line 1 is not currently used) and 8 (same design as workshop7).				

09/11/2017	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential