Veterinary Medicines Directorate

Certificate No: VMDGMP/M114/2021

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC as amended.

The competent authority of: UNITED KINGDOM (***Veterinary***) confirms the following:

The manufacturer: **Qilu SYNVA Pharmaceutical Co. Ltd**

Site address: No. 28 Licheng Ave.,
Linyi County
Shandong
China 251500

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 80(4) of Directive 2001/82/EC transposed in the following national legislation:

The Current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **20-23 March 2018**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

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 on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: Confidential

Date: 13 December 2023

Name: Confidential

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone +44 (0)1932 336911
Search for VMD on GOV.UK

Part 2

Veterinary Medicinal Products

1.	**MANUFACTURING OPERATIONS**
1.1	Sterile Products: N/A
1.2	Non-sterile products: N/A
1.3	Biological medicinal products: N/A
1.4	Other products or manufacturing activity: 1.4.2 Sterilisation of active substance 1.4.2.1 Filtration 1.4.3 Micronisation
1.5	Packaging: N/A
1.6	Quality Control testing: 1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate:

This scope of this certificate is limited to workshop 3, where final processing steps for sterile active substance are conducted.

Political and logistical complications relating to travel to China. Although Covid-19 related travel restrictions were relaxed in 2023 these other complications and uncertainty due to high Covid-19 levels in China following relaxation of the past travel restrictions, prevented organisation of inspections in 2023. Following a review of the risk assessment, it is considered that the validity of the GMP certificate for the site can be extended to the end of 2024. This extension does not prevent scheduling of an on-site inspection of the site at any point in 2024 when this is possible.

Name and signature of the authorised person of the Competent Authority of the UK:

Signature: Confidential

Date: 13 December 2023

Name: Confidential

Veterinary Medicines Directorate
tel: Confidential
email: Confidential