Veterinary Medicines Directorate

Certificate No: VMDGMP/M201/2024

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Non-UK Manufacturer

Part 1

Issued following an inspection in accordance with Schedule 2 of the Veterinary Medicines Regulations 2013 (as amended) as it has effect in Northern Ireland and Great Britain.

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 United Kingdom in accordance with Good Manufacturing Practice (GMP).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **21-24 May 2024**, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice as required by the Veterinary Medicines Regulations 2013 (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 EudraGMP or on GOV.UK. If it does not appear, please contact the issuing authority.

Signature: CONFIDENTIAL

Name: CONFIDENTIAL

Date: 13 August 2024

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.

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

Signature: CONFIDENTIAL

Date: 13 August 2024

Name: CONFIDENTIAL