



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: **Shandong Lukang Shelile Pharmaceutical Co. Ltd**

Site address: **50 Hualu Road
Jining
Shandong
China
272021**

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 **17 - 18 December 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 in EudraGMP. If it does not appear, please contact the issuing authority.

Signature: Confidential

Date: 11 February 2019

Name: Confidential

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS	
1.1	Sterile Products: Not applicable
1.2	Non-sterile products: 1.2.17 other (API processing – granulation)
1.3	Biological medicinal products: Not applicable
1.4	Other products or manufacturing activity: Not applicable
1.5	Packaging: Not applicable
1.6	Quality Control testing: 1.6.3 Chemical/Physical

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

The scope of this certificate is limited to building 7 (2nd floor Workshop 602), building 16, building 20 and building 35 at 50 Hualu Road.

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

Confidential

Signature: _____

Date: 11 February 2019

Name: Confidential

Veterinary Medicines Directorate
tel: Confidential
email: Confidential