Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 16776 Insp GMP/IMP 16776/8489-0015

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The competent authority of the United Kingdom confirms the following:

The manufacturer	MOREDUN SCIENTIFIC LIMITED
Site address	PENTLANDS SCIENCE PARK BUSH LOAN PENICUIK EH26 0PZ UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with Art. 111(1) of Directive 2001/83/EC (or Article 80(1) of Directive 2001/82/EC) transposed in the following national legislation: For human medicines 'The Medicines Act 1968 as amended'; for veterinary medicines 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20/03/2019, 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 only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.

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Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

1.6.1 Microbiological: sterility
1.6.2 Microbiological: non-sterility
1.6.4 Biological

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility
2.1.2 Microbiological: non-sterility
2.1.4 Biological

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

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

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. A risk-based site inspection programme remains in force.

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   The site performs microbiology testing including sterility testing and mycoplasma testing. The site also undergoes GLP inspections.
   Biological tests are performed as well as biosafety testing, potency, efficacy and safety tests for adventitious agents etc.

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 20/03/2019