Certificate No: UK API 39930 Insp GMP 39930/3649399-0006

MHRA
Regulating Medicines and Medical Devices

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	PEPCEUTICALS LIMITED
Site address	4 FELDSPAR CLOSE ENDERBY LEICESTER LE19 4JS UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Art. 80(1) 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 26/09/2017, it is considered that it complies with the principles of GMP for active substances

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.

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

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

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ACTIVE SUBSTANCES FOR CLINICAL TRIALS

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates
3.1.2 Manufacture Of Crude Active Substance
3.1.3 Salt Formation/Purification Steps (e.g. Crystallisation)
Synthetically manufactured peptides are purified.

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

3.3.3 Isolation / Purification

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

4 Other Activities

Not Authorised

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

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

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

   manufacture of peptide API for Investigational Medicinal Products

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

Graeme McKilligan
GMP Inspector
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Date: 23/11/2017