Certificate No: UK ManA 28255 Insp GMP 28255/123039-0008

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	RUTLAND BIODYNAMICS LIMITED
Site address	TOWN PARK FARM OAKHAM ROAD BROOKE OAKHAM LE15 8DG UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ManA 28255 in accordance with Art. 44 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 02/06/2015, 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

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.5 Liquids for external use
1.2.1.17 Other non-sterile medicinal products
Traditional Herbal products

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.1 Manufacture of

1.4.1.1 Herbal products
1.4.1.3 Other
Hopguard, Liquid topical ectoparasitic for bees (minor use, minor species)

1.5 Packaging

1.5.1 Primary packaging

1.5.1.5 Liquids for external use
1.5.2 Secondary packaging

1.6 Quality control testing

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.2 Microbiological: non-sterility
2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

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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:

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)

   N/A

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

Ewan Norton
GMP Inspector
Ewan.Norton@mhra.gsi.gov.uk

Date: 09/01/2017