Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK MIA(IMP) 49464 Insp IMP 49464/18321324-0003

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	ENTEROBIOTIX LIMITED
Site address	ABERDEEN BLOOD TRANSFUSION CENTRE FORESTERHILL ROAD ABERDEEN AB25 2ZW UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA(IMP) 49464 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: 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 07/05/2019, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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

Human Investigational Medicinal Products for phase I, II, III clinical trials

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)

1.2.1.6 Liquids for internal use
1.2.1.17 Other non-sterile medicinal products
FAECAL MICROBIOTA

1.2.2 Batch Certification

1.3 Biological medicinal products

1.3.1 Biological medicinal products

1.3.1.6 Human or animal extracted products
1.3.1.8 Other biological medicinal products
FAECAL MICROBIOTA

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.1 Primary packaging

1.5.1.6 Liquids for internal use
1.5.1.17 Other non-sterile medicinal products
FAECAL MICROBIOTA

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility

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

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:

Secondary packaging of IMPs is approved for open-label studies only and does not involve labelling for blinded studies.

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

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

Date: 23/05/2019