Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK MIA(IMP) 6180 Insp GMP/IMP 6180/17741-0016

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	SYNERGY HEALTH STERILISATION UK LIMITED
Site address	MORAY ROAD ELGIN INDUSTRIAL ESTATE SWINDON SN2 8XS UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA(IMP) 6180 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 12/11/2018, 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.

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

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.2 Sterilisation of active substances/excipients/finished product

1.4.2.5 Gamma irradiation

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

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

Certificate No: UK MIA(IMP) 6180 Insp GMP/IMP 6180/17741-0016

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

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

Date: 04/03/2019