Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 46345 Insp IMP 46345/14583918-0006[I]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : IMP PHARMACEUTICAL SERVICES LIMITED

Site address : IMP PHARMACEUTICAL SERVICES LIMITED, UNIT 23, WOODFIELDSIDE BUSINESS PARK, PENMAEN ROAD, PONTLLANFRAITH, BLACKWOOD, NP12 2DG, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 46345 in accordance with Part 6 of 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 07/12/2021 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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 valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

Virus seed storage

[1.3.1.5] Biotechnology products

Virus seed storage

[1.3.1.8] Other biological medicinal products

Zika Master Virus Seed Storage

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.4] Gene therapy products

Virus seed storage

[1.3.2.5] Biotechnology products

Virus seed storage

[1.5] Packaging

[1.5.2] Secondary packaging

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.2] Immunological products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.8] Other biological medicinal products

Zika Master Virus Seed Storage

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list

Restrictions or Remarks

Focussed OBI to assess oversight process for IMP importation from a listed country.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
				Virus seed activities restricted to storage / handling only.

07/12/2021	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential