Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 46345
2: Name of authorisation holder	IMP PHARMACEUTICAL SERVICES LIMITED
3: Address(es) of manufacturing site(s)	IMP PHARMACEUTICAL SERVICES LIMITED, UNIT 23, WOODFIELDSIDE BUSINESS PARK, PENMAEN ROAD, PONTLLANFRAITH, BLACKWOOD, NP12 2DG, UNITED KINGDOM IMP PHARMACEUTICAL SERVICES LIMITED, UNIT 29, WOODFIELDSIDE BUSINESS PARK, PENMAEN ROAD, PONTLLANFRAITH, BLACKWOOD, NP21 2DG, UNITED KINGDOM
4: Legally registered address of authorisation holder	IMP PHARMACEUTICAL SERVICES LIMITED, UNIT 23, WOODFIELDSIDE BUSINESS PARK, PENMAEN ROAD, PONTLLANFRAITH, BLACKWOOD, NP12 2DG, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	07/12/2021
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 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

Special Requirements

Virus seed storage

[1.3.1.5] Biotechnology products

Special Requirements

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

Special Requirements

Virus seed storage

[1.3.2.5] Biotechnology products

Special Requirements

Virus seed storage

[1.5] Packaging

[1.5.2] Secondary packaging

Part 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

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

IMP PHARMACEUTICAL SERVICES LIMITED, UNIT 29, WOODFIELDSIDE BUSINESS PARK, PENMAEN ROAD, PONTLLANFRAITH, BLACKWOOD, NP21 2DG, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

Special Requirements

Virus seed storage

[1.3.1.5] Biotechnology products

Special Requirements

Virus seed storage

[1.3.1.8] Other biological medicinal products

Zika Master Virus Seed Storage

Part 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

[2.2.3.8] Other biological medicinal products

Zika Master Virus Seed Storage

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

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