

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**IMP PHARMACEUTICAL SERVICES LIMITED**, UNIT 23, WOODFIELDSDIE 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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 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:

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<p><b>Part 1 - MANUFACTURING OPERATIONS</b></p> <p><b>[ 1.3 ] Biological investigational medicinal products</b></p> <p>[ 1.3.1 ] Biological medicinal products</p> <p>[ 1.3.1.4 ] Gene therapy products</p> <p><b>Special Requirements</b></p> <p>Virus seed storage</p> <p>[ 1.3.1.5 ] Biotechnology products</p> <p><b>Special Requirements</b></p> <p>Virus seed storage</p> <p>[ 1.3.1.8 ] Other biological medicinal products</p> <p>Zika Master Virus Seed Storage</p> <p><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b></p> <p><b>[ 2.2 ] Batch certification of imported medicinal products</b></p> <p>[ 2.2.1 ] Sterile Products</p> <p>[ 2.2.1.1 ] Aseptically prepared</p> <p>[ 2.2.1.2 ] Terminally sterilised</p> <p>[ 2.2.2 ] Non-sterile products</p> <p>[ 2.2.3 ] Biological medicinal products</p> <p>[ 2.2.3.2 ] Immunological products</p> <p>[ 2.2.3.4 ] Gene therapy products</p> <p>[ 2.2.3.8 ] Other biological medicinal products</p> <p>Zika Master Virus Seed Storage</p> <p><b>[ 2.3 ] Other Importation Activities</b></p> <p>[ 2.3.1 ] Site of Physical Importation</p> <p>[ 2.3.2 ] Importation of Intermediate which undergoes further processing</p> <p>[ 2.3.4 ] Other</p> <p>Importation of QP certified IMPs from a country on the approved country for import list</p>