

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 57623
<b>2: Name of authorisation holder</b>	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, 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>	24/05/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED**, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, 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> [ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms) [ 1.1.1.4 ] Small volume liquids <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.6 ] Liquids for internal use

- [ 1.2.1.15 ] Other non-sterile medicinal products  
Manufacture of low bioburden bulk drug substance solutions.

### **[ 1.3 ] Biological investigational medicinal products**

- [ 1.3.1 ] Biological medicinal products
  - [ 1.3.1.2 ] Immunological products
  - [ 1.3.1.4 ] Gene therapy products
  - [ 1.3.1.5 ] Biotechnology products
  - [ 1.3.1.8 ] Other biological medicinal products  
Antibodies, antibody conjugates Live microbial products; Therapeutic Virus; Plant extracted materials.
- [ 1.3.2 ] Batch certification
  - [ 1.3.2.2 ] Immunological products
  - [ 1.3.2.4 ] Gene therapy products
  - [ 1.3.2.5 ] Biotechnology products

### **[ 1.4 ] Other investigational medicinal products or manufacturing activity**

- [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:
  - [ 1.4.2.1 ] Filtration
  - [ 1.4.2.3 ] Moist heat

### **[ 1.6 ] Quality control testing**

- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical
- [ 1.6.4 ] Biological

## **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

### **[ 2.1 ] Quality control testing of imported medicinal products**

- [ 2.1.2 ] Microbiological: non-sterility
- [ 2.1.3 ] Chemical/Physical
- [ 2.1.4 ] Biological

### **[ 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
  - [ 2.2.3.3 ] Cell therapy products
  - [ 2.2.3.4 ] Gene therapy products
  - [ 2.2.3.5 ] Biotechnology products
  - [ 2.2.3.6 ] Human or animal extracted products
  - [ 2.2.3.8 ] Other biological medicinal products  
Antibodies, antibody conjugates Live microbial products; Therapeutic Virus; Plant extracted materials.