Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 57623
2: Name of authorisation holder	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED
3: Address(es) of manufacturing site(s)	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, UNITED KINGDOM
4: Legally registered address of authorisation holder	CHARLES RIVER DISCOVERY RESEARCH SERVICES UK LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	24/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

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 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 Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

Special Requirements

Pathogenic Organisms (Biosafety Level 3 or 4)

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.6] Liquids for internal use

Special Requirements

Live Cells

[1.2.1.17] Other non-sterile medicinal products

Manufacture of low bioburden bulk drug substance solutions

Special Requirements

Live Cells

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

Special Requirements

Live Cells

[1.3.1.4] Gene therapy products

Special Requirements

Live Cells

[1.3.1.5] Biotechnology products

Special Requirements

Live Cells

[1.3.1.8] Other biological medicinal products

Antibodies,Antibody conjugates, Live microbial products, Therapeutic Virus, Plant extracted materials

Special Requirements

Live Cells

[1.3.2] Batch certification

[1.3.2.2] Immunological products

Special Requirements

Live Cells

[1.3.2.4] Gene therapy products

Special Requirements

Live Cells

[1.3.2.5] Biotechnology products

Special Requirements

Live Cells

[1.4] Other 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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing