

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

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| 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