Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 17136
2: Name of authorisation holder	NEWCASTLE-UPON-TYNE HOSPITALS NHS FOUNDATION TRUST
3: Address(es) of manufacturing site(s)	NEWCASTLE ADVANCED THERAPIES CFL, BIOSCIENCE CENTRE, INTERNATIONAL CENTRE FOR LIFE, TIMES SQUARE, NEWCASTLE UPON TYNE, NE1 3BZ, UNITED KINGDOM ROYAL VICTORIA INFIRMARY T/A PHARMACEUTICAL SERVICES, ROYAL VICTORIA INFIRMARY, QUEEN VICTORIA ROAD, NEWCASTLE UPON TYNE, NE1 4LP, UNITED KINGDOM
4: Legally registered address of authorisation holder	NEWCASTLE-UPON-TYNE HOSPITALS NHS FOUNDATION TRUST, ROYAL VICTORIA INFIRMARY, QUEEN VICTORIA ROAD, NEWCASTLE UPON TYNE, NE1 4LP, 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	15/02/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

NEWCASTLE ADVANCED THERAPIES CFL, BIOSCIENCE CENTRE, INTERNATIONAL CENTRE FOR LIFE, TIMES SQUARE, NEWCASTLE UPON TYNE, NE1 3BZ, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

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

[1.1.1.6] Other aseptically prepared products

Cellular therapies, tissue engineered products

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.8] Other biological medicinal products

Tissue Engineered Products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

Quality Control Testing - Microbiological: non-sterility restricted to Gram Stain

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ROYAL VICTORIA INFIRMARY T/A PHARMACEUTICAL SERVICES, ROYAL VICTORIA INFIRMARY, QUEEN VICTORIA ROAD, NEWCASTLE UPON TYNE, NE1 4LP, 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

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

[1.1.1.1] Large volume liquids

[1.1.1.3] Semi-solids

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products

Eyedrops

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.3] Small volume liquids

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.1] Capsules, hard shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.12] Suppositories

[1.2.1.15] Other non-sterile medicinal products

Lollipops, Primary Packing: Powders

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[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

[2.2] 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

[2.3] Other Importation Activities

[2.3.4] Other

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