

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 17328

2: Name of authorisation holder GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST

3: Address(es) of manufacturing site(s) ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN, 20 GUILFORD STREET, LONDON, WC1N 1DZ, UNITED KINGDOM

4: Legally registered address of authorisation holder GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, GENE AND CELL THERAPY, GREAT ORMOND STREET, LONDON, WC1N 3JH, 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 26/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN, 20 GUILFORD STREET, LONDON, WC1N 1DZ, 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)

[1.1.1.4] Small volume liquids

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.4] Gene therapy products

Special Requirements

Viral vectors

[1.3.1.5] Biotechnology products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

Special Requirements

Viral vectors

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activities

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[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:

GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, GENE AND CELL THERAPY, GREAT ORMOND STREET, LONDON, WC1N 3JH, 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) [1.1.1.4] Small volume liquids

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.4] Gene therapy products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[1.1] Sterile Investigational Medicinal Products

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

[1.1.1.4] Small volume liquids

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

[1.3.1.4] Gene therapy products

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[2.3] Other Importation Activities

[2.3.4] Other

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