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 ZAYED CENTRE FOR RESEARCH INTO RARE DISEASE IN CHILDREN, 20 GUILFORD STREET, LONDON, WC1N 1DZ, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, GENE AND CELL THERAPY, GREAT ORMOND STREET, LONDON, WC1N 3JH, UNITED KINGDOM
4: Legally registered address of authorisation holder	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST, 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	11/10/2024
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 activitiy

[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
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Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

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[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

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[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