

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 17479
2: Name of authorisation holder	OXFORD BIOMEDICA (UK) LIMITED OXFORD BIOMEDICA (UK) LIMITED, UNIT A, PLOT 7000, ALEC ISSIGONIS WAY, OXFORD, OX4 2ZY, UNITED KINGDOM OXFORD BIOMEDICA (UK) LIMITED, UNIT 5, OXFORD PIONEER PARK, MEAD ROAD, YARNTON, KIDLINGTON, OXFORD, OX5 1QU, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	OXFORD BIOMEDICA (UK) LIMITED, COUNTY TRADING ESTATE, WATLINGTON ROAD, OXFORD, OX4 6LX, UNITED KINGDOM OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT, TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM
4: Legally registered address of authorisation holder	OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT, WATLINGTON ROAD, OXFORD, OX4 6LT, 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	25/07/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

OXFORD BIOMEDICA (UK) LIMITED, UNIT A, PLOT 7000, ALEC ISSIGONIS WAY, OXFORD, OX4 2ZY, 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)
 - [1.1.1.4] Small volume liquids
- [1.1.3] Batch certification

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.2] Immunological products
 - [1.3.1.3] Cell therapy products
 - [1.3.1.4] Gene therapy products
 - [1.3.1.5] Biotechnology products
- [1.3.2] Batch certification
 - [1.3.2.2] Immunological products
 - [1.3.2.3] Cell therapy products
 - [1.3.2.4] Gene therapy products
 - [1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.1] Manufacture of:
 - [1.4.1.3] Other
 - Biological active starting materials
- [1.4.2] Sterilisation of active substances/excipients/finished products:
 - [1.4.2.1] Filtration

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.6] Liquids for internal use
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.1] Microbiological: sterility
- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

OXFORD BIOMEDICA (UK) LIMITED, UNIT 5, OXFORD PIONEER PARK, MEAD ROAD, YARNTON, KIDLINGTON, OXFORD, OX5 1QU, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.2] Immunological products
 - [1.3.1.3] Cell therapy products
 - [1.3.1.4] Gene therapy products
 - [1.3.1.5] Biotechnology products
- [1.3.2] Batch certification
 - [1.3.2.2] Immunological products
 - [1.3.2.3] Cell therapy products
 - [1.3.2.4] Gene therapy products
 - [1.3.2.5] Biotechnology products
- [1.4] Other investigational medicinal products or manufacturing activity**
 - [1.4.1] Manufacture of:
 - [1.4.1.3] Other
 - Biological active starting materials
- [1.6] Quality control testing**
 - [1.6.2] Microbiological: non-sterility

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

OXFORD BIOMEDICA (UK) LIMITED , COUNTY TRADING ESTATE, WATLINGTON ROAD, OXFORD, OX4 6LX, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<p>Part 1 - MANUFACTURING OPERATIONS</p> <ul style="list-style-type: none"> [1.3] Biological investigational medicinal products <ul style="list-style-type: none"> [1.3.1] Biological medicinal products <ul style="list-style-type: none"> [1.3.1.2] Immunological products [1.3.1.3] Cell therapy products [1.3.1.4] Gene therapy products [1.3.1.5] Biotechnology products [1.3.2] Batch certification <ul style="list-style-type: none"> [1.3.2.2] Immunological products [1.3.2.3] Cell therapy products [1.3.2.4] Gene therapy products [1.3.2.5] Biotechnology products [1.4] Other investigational medicinal products or manufacturing activity <ul style="list-style-type: none"> [1.4.1] Manufacture of: <ul style="list-style-type: none"> [1.4.1.3] Other <ul style="list-style-type: none"> Biological active starting materials

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT, TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.6] Quality control testing [1.6.3] Chemical/Physical [1.6.4] Biological