

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 17479
2: Name of authorisation holder	OXFORD BIOMEDICA (UK) LIMITED 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, WINDRUSH COURT, TRANSPORT WAY, OXFORD, OX4 6LT, UNITED KINGDOM OXFORD BIOMEDICA (UK) LIMITED, UNIT A, PLOT 7000, ALEC ISSIGONIS WAY, OXFORD, OX4 2ZY, UNITED KINGDOM OXFORD BIOMEDICA (UK) LIMITED, COUNTY TRADING ESTATE, WATLINGTON ROAD, OXFORD, OX4 6LX, UNITED KINGDOM
4: Legally registered address of authorisation holder	OXFORD BIOMEDICA (UK) LIMITED, WINDRUSH COURT, TRANSPORT WAY, OXFORD, OX4 6LT, 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	25/07/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

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 Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological 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 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 1

Name and address of the site:

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

Human 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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

OXFORD BIOMEDICA (UK) LIMITED, UNIT A, PLOT 7000, ALEC ISSIGONIS WAY, OXFORD, OX4 2ZY, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

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

[1.1.3] Batch certification

[1.3] Biological 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 products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Biological active starting materials

[1.4.1.4] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)

[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 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological 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 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