

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 44168

2: Name of authorisation holder INSTIL BIO (UK) LIMITED

3: Address(es) of manufacturing site(s) INSTIL BIO (UK) LIMITED, 46 GRAFTON STREET, MANCHESTER, M13 9NT, UNITED KINGDOM

4: Legally registered address of authorisation holder INSTIL BIO (UK) LIMITED, UNIVERSITY OF MANCHESTER INNOVATION CENTRE, BIOINCUBATOR BUILDING, 48 GRAFTON STREET, MANCHESTER, M13 9XX, 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 12/03/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

INSTIL BIO (UK) LIMITED, 46 GRAFTON STREET, MANCHESTER, M13 9NT, 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

[1.1.1.6] Other aseptically prepared products

Autologous cell therapies using cells extracted from human tissues prior to manipulation. The final product is made up as a cell suspension for re-infusion

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

[1.3.2] Batch certification

[1.3.2.4] Gene therapy products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.2] Secondary packaging

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

INSTIL BIO (UK) LIMITED, UNIVERSITY OF MANCHESTER INNOVATION CENTRE, BIOINCUBATOR BUILDING, 48 GRAFTON STREET, MANCHESTER, M13 9XX, 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

Autologous cellular therapies for direct infusion. Allogenic cell therapies

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

[1.1.2.3] 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

[1.3.1.8] Other biological medicinal products

Autologous cellular therapies using cells extracted from human tissue prior to manipulation. The final product is made up as a cell suspension for re-infusion. Allogenic cell therapies

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

[1.3.2.4] Gene therapy products

[1.3.2.8] Other biological medicinal products

Autologous cellular therapies using cells extracted from human tissue prior to manipulation. The final product is made up as a cell suspension for re-infusion. Allogeneic cell therapies

[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

[1.6.3] Chemical/Physical

[1.6.4] Biological