

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 49239
2: Name of authorisation holder	ACHILLES THERAPEUTICS UK LIMITED
3: Address(es) of manufacturing site(s)	ACHILLES THERAPEUTICS UK LIMITED, CELL AND GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, UNITED KINGDOM
4: Legally registered address of authorisation holder	ACHILLES THERAPEUTICS UK LIMITED, 245 HAMMERSMITH ROAD, LONDON, W6 8PW, 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	14/08/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ACHILLES THERAPEUTICS UK LIMITED, CELL AND GENE THERAPY CATAPULT MANUFACTURING CENTRE, GUNNELS WOOD ROAD, STEVENAGE, SG1 2FX, 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

Special Requirements

Live Cells

[1.1.1.6] Other aseptically prepared products

Live cells

Special Requirements

Live Cells

[1.1.3] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.3] Cell therapy products

Special Requirements

Live Cells

[1.3.1.6] Human or animal extracted products

Special Requirements

Live Cells

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

Special Requirements

Live Cells

[1.3.2.6] Human or animal extracted products

Special Requirements

Live Cells

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Environmental monitoring or process simulation (media fill) to support sterile manufacture

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological