Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 46616
2: Name of authorisation holder	REPLIMUNE LIMITED
3: Address(es) of manufacturing site(s)	REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED KINGDOM
4: Legally registered address of authorisation holder	REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, 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	21/04/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

REPLIMUNE LIMITED, 69 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RQ, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

MHRA-GMDP MHRA-GMDP MHRA

[1.3.1.4] Gene therapy products

Special Requirements

Selectively replication competent Herpes simplex virus that contain various transgenes intended to simulate immune responses. These products are administered by direct tumour injection into suitable non-neurological solid tumours

[1.3.2] Batch certification

[1.3.2.4] Gene therapy products

Special Requirements

Selectively replication competent Herpes simplex virus that contain various transgenes intended to simulate immune responses. These products are administered by direct tumour injection into suitable non-neurological solid tumours

[1.3.2.5] Biotechnology products

Special Requirements

According to the commercial product SmPC

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological

MHRA-GMDP MHRA-GMDP MHRA MHRA