Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 32954
2: Name of authorisation holder	EXMOOR PHARMA CONCEPTS LIMITED
3: Address(es) of manufacturing site(s)	EXMOOR PHARMA CONCEPTS LTD, CELL & GENE THERAPY CENTRE, BRITANNIA ROAD, BRISTOL, BS34 5TA, UNITED KINGDOM
4: Legally registered address of authorisation holder	EXMOOR PHARMA CONCEPTS LIMITED, CELL & GENE THERAPY CENTRE, BRITANNIA ROAD, BRISTOL, BS34 5TA, 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	12/09/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

EXMOOR PHARMA CONCEPTS LTD, CELL & GENE THERAPY CENTRE, BRITANNIA ROAD, BRISTOL, BS34 5TA, 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

[1.1.3] 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

[1.3.1.4] Gene therapy products

Special Requirements

Live Cells

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products

Manufacture of Mamalian Cell Bank

[1.3.2] Batch certification

[1.3.2.3] Cell therapy products

Special Requirements

Live Cells

[1.3.2.4] Gene therapy products

Special Requirements

Live Cells

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

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

[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

[1.6.3] Chemical/Physical

[1.6.4] Biological