

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 32954
<b>2: Name of authorisation holder</b>	EXMOOR PHARMA CONCEPTS LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	EXMOOR PHARMA CONCEPTS LTD, CELL & GENE THERAPY CENTRE, BRITANNIA ROAD, BRISTOL, BS34 5TA, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	EXMOOR PHARMA CONCEPTS LIMITED, CELL & GENE THERAPY CENTRE, BRITANNIA ROAD, BRISTOL, BS34 5TA, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	12/09/2024
<b>9: Annexes attached</b>	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 activity**

[ 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