

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

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| 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