

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 53553
2: Name of authorisation holder	CENTRAL PHARMA CELL AND GENE THERAPY LTD
3: Address(es) of manufacturing site(s)	CENTRAL PHARMA CELL AND GENE THERAPY LTD, UNITS C AND D, HOMEFIELD BUSINESS PARK, HOMEFIELD ROAD, HAVERHILL, CB9 8QP, UNITED KINGDOM
4: Legally registered address of authorisation holder	CENTRAL PHARMA CELL AND GENE THERAPY LTD, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	10/09/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CENTRAL PHARMA CELL AND GENE THERAPY LTD, UNITS C AND D, HOMEFIELD BUSINESS PARK, HOMEFIELD ROAD, HAVERHILL, CB9 8QP, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.13] Tablets [1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing