

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 27794  |
| <b>2: Name of authorisation holder</b>  | CENTRAL PHARMA CONTRACT PACKING LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | CENTRAL PHARMA CELL AND GENE THERAPY LTD, UNITS C AND D, HOMEFIELD BUSINESS PARK, HOMEFIELD ROAD, HAVERHILL, CB9 8QP, UNITED KINGDOM<br>CENTRAL PHARMA (CONTRACT PACKING) LIMITED, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | CENTRAL PHARMA CONTRACT PACKING LIMITED, CAXTON ROAD, ELM FARM INDUSTRIAL ESTATE, BEDFORD, MK41 0XZ, UNITED KINGDOM   |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)  |
| <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>  | 29/01/2025  |
| <b>9: Annexes attached</b>  | 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)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                    |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.2 ] Batch certification<br><b>[ 1.5 ] Packaging</b> |

- [ 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

**[ 1.6 ] Quality control testing**

- [ 1.6.3 ] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**[ 2.3 ] Other Importation Activities**

- [ 2.3.1 ] Site of Physical Importation
- [ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**CENTRAL PHARMA (CONTRACT PACKING) LIMITED, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM**

|   |
|---|
| Human Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.1 ] Sterile Products**

- [ 1.1.3 ] Batch certification

**[ 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
  - [ 1.5.1.5 ] Liquids for external use
  - [ 1.5.1.6 ] Liquids for internal use
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.9 ] Pressurised preparations
  - [ 1.5.1.13 ] Tablets
  - [ 1.5.1.17 ] Other non-sterile medicinal products

Assembly of pressurised aerosols and sterile products. Previously sealed hormones and cytotoxic/cytostatic products.

Secondary packaging of penicillin.

- [ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.3 ] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.1 ] Sterile Products

[ 2.2.1.1 ] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[ 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