Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 27794
2: Name of authorisation holder	CENTRAL PHARMA CONTRACT PACKING LIMITED
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 CENTRAL PHARMA (CONTRACT PACKING) LIMITED, CAXTON ROAD, BEDFORD, MK41 0XZ, UNITED KINGDOM
4: Legally registered address of authorisation holder	CENTRAL PHARMA CONTRACT PACKING LIMITED, CAXTON ROAD, ELM FARM INDUSTRIAL ESTATE, 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	31/01/2024
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)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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) 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

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.2] Capsules, soft shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

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