

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 25274

2: Name of authorisation holder CATALENT CTS (EDINBURGH) LIMITED

3: Address(es) of manufacturing site(s) CATALENT CTS (EDINBURGH) LIMITED, UNIT 1
INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED
KINGDOM

4: Legally registered address of authorisation holder CATALENT CTS (EDINBURGH) LIMITED, FRANKLAND
ROAD, BLAGROVE, SWINDON, SN5 8YG, 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 10/12/2021

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CATALENT CTS (EDINBURGH) LIMITED, UNIT 1 INCHWOOD PARK, BATHGATE, EH48 2FY, UNITED KINGDOM

Human Investigational Medicinal Products
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Authorised Operations

MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.1] Blood products

- [1.3.2.2] Immunological products
- [1.3.2.3] Cell therapy products
- [1.3.2.4] Gene therapy products
- [1.3.2.5] Biotechnology products
- [1.3.2.6] Human or animal extracted products

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.1] Capsules, hard shell
 - [1.5.1.2] Capsules, soft shell
 - [1.5.1.3] Chewing gums
 - [1.5.1.4] Impregnated matrices
 - [1.5.1.8] Other solid dosage forms
 - [1.5.1.11] Semi-solids
 - [1.5.1.12] Suppositories
 - [1.5.1.13] Tablets
 - [1.5.1.14] Transdermal patches
 - [1.5.1.15] Other non-sterile medicinal products

Cytostatics, cytotoxics, hormone products may undergo primary packaging, pessaries
- [1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[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
- [2.2.3] Biological medicinal products
 - [2.2.3.1] Blood products
 - [2.2.3.2] Immunological products
 - [2.2.3.3] Cell therapy products
 - [2.2.3.4] Gene therapy products
 - [2.2.3.5] Biotechnology products
 - [2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

- [2.3.1] Site of Physical Importation
- [2.3.2] Importation of Intermediate which undergoes further processing
- [2.3.4] Other
 - Importation of QP-certified IMPs from a country on the approved country for import list