Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 25274 Insp GMP/GDP/IMP 25274/29333-0019[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : CATALENT CTS (EDINBURGH) LIMITED

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

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 25274 in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 07/02/2022 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.3] Biological medicinal products

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[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

[1.5.2] Secondary packaging

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

26/04/2022	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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