Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 5451 Insp GMP/IMP 5451/16389-0021[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 MICRON TECHNOLOGIES LIMITED

Site address : CATALENT MICRON TECHNOLOGIES LIMITED , CROSSWAYS BOULEVARD, CROSSWAYS, DARTFORD, DA2 6QY, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 5451 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 21/06/2022 , 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

[1.2] Non-sterile products

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

[1.2.1.17] Other non-sterile medicinal products

Particle size reduction by Micronisation/milling of API and excipients and blends. Steroids and hormones are occasionally handled within the facility and non sensitising antibiotics.

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[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.8] Other solid dosage forms

[1.5.1.17] Other non-sterile medicinal products

APIs, excipients and blends. Occasional packing of steroids, hormones and non-sensitizing antibiotics

[1.6] Quality control testing

[1.6.3] Chemical/Physical

27/07/2022	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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