# Medicines and Healthcare products Regulatory Agency

## CERTIFICATE NUMBER : UK ManA 5451 Insp GMP 5451/16389-0022[V]

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

# Part 1

Issued following an inspection in accordance with :
Regulation 5 of the current Veterinary Medicines Regulations

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 ManA 5451 in accordance with Regulation 5 of The current Veterinary Medicines Regulations

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 5 of the current Veterinary Medicines Regulations

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.

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- *(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

**Veterinary Medicinal Products**

**1. MANUFACTURING OPERATIONS**

**[ 1.2 ] Non-sterile products**

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

[ 1.2.1.8 ] Other solid dosage forms

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[ 1.2.1.17 ] Other non-sterile medicinal products

Particle size reduction by Micronisation - milling of APIs, excipients and blends. Steroids and hormones are occasionally handled at the facility. No feedstuffs such as wheat, oil or soya will be processed and no pellets manufactured.

[ 1.2.2 ] Batch certification

**[ 1.4 ] Other products or manufacturing activity**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.3 ] Other

Particle size reduction by Micronisation - milling of APIs, excipients and blends. Steroids and hormones are occasionally handled at the facility. No Feedstuffs such as wheat, oil or soya will be processed and no pellets manufactured

**[ 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, blends, steroids and hormones

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

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| 18/08/2022 | Name and signature of the authorised person of the Competent Authority of United Kingdom<br>Confidential<br>Medicines and Healthcare products Regulatory Agency<br>Tel : Confidential |

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