

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK ManA 5451

2: Name of authorisation holder CATALENT MICRON TECHNOLOGIES LIMITED

3: Address(es) of manufacturing site(s) CATALENT MICRON TECHNOLOGIES LIMITED , CROSSWAYS BOULEVARD, CROSSWAYS, DARTFORD, DA2 6QY, UNITED KINGDOM

4: Legally registered address of authorisation holder CATALENT MICRON TECHNOLOGIES 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 Regulation 5 of the current Veterinary Medicines Regulations

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 26/02/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Veterinary Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS 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 [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