

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK ManA 5451
<b>2: Name of authorisation holder</b>	CATALENT MICRON TECHNOLOGIES LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	CATALENT MICRON TECHNOLOGIES LIMITED , CROSSWAYS BOULEVARD, CROSSWAYS, DARTFORD, DA2 6QY, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	CATALENT MICRON TECHNOLOGIES LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8YG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 5 of the current Veterinary Medicines Regulations
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	26/02/2024
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> 1. MANUFACTURING OPERATIONS <b>[ 1.2 ] Non-sterile products</b> [ 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 <b>[ 1.4 ] Other products or manufacturing activity</b>

[ 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