

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number**

UK MIA(IMP) 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**

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

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

Confidential

**8: Authorisation Date**

22/12/2025

**9: Annexes attached**

Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b>
<b>[ 1.2 ] Non-sterile investigational medicinal products</b>
[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)
[ 1.2.1.15 ] 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. Non sensitising antibiotics.
[ 1.2.2 ] Batch certification
<b>[ 1.5 ] Packaging</b>
[ 1.5.1 ] Primary packaging

[ 1.5.1.15 ] 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

MHRA-GMDP