

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 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>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<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 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)

#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.2 ] Non-sterile investigational medicinal products

[ 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

##### [ 1.5 ] Packaging

[ 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