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)

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

MHRA-GMDP MHRA

[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 MHRA MHRA-GMDP MHRA