Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 36456
2: Name of authorisation holder	CATALENT NOTTINGHAM LIMITED
3: Address(es) of manufacturing site(s)	CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, UNITED KINGDOM
4: Legally registered address of authorisation holder	CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, 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	31/01/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

[1.2.1.15] Other non-sterile medicinal products

Orodispersible tablets, Oral Powder Blends/ Process API through Suupercritical Fluid rig to modifyits physical properties only prior to processing

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing