Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 36456

2: Name of authorisation holder CATALENT NOTTINGHAM LIMITED

CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX, 3: Address(es) of manufacturing site(s)

UNITED KINGDOM

CATALENT NOTTINGHAM LIMITED, 8 ORCHARD PLACE, 4: Legally registered address of authorisation holder

NOTTINGHAM BUSINESS PARK, NOTTINGHAM, NG8 6PX,

UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 6: Legal Basis of authorisation

2012/1916)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

8: Authorisation Date 05/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

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

[1.2.1.13] Tablets

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.13] Tablets

Issue Date: 05 Jun 2024

