

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 14023

2: Name of authorisation holder CATALENT UK SWINDON ZYDIS LIMITED

3: Address(es) of manufacturing site(s) CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, UNITED KINGDOM

4: Legally registered address of authorisation holder CATALENT UK SWINDON ZYDIS LIMITED, 1 GEORGE SQUARE, GLASGOW, G2 1AL, UNITED KINGDOM

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

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

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

8: Authorisation Date 16/04/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, 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 [1.2.1.17] Other non-sterile medicinal products Freeze dried tablet (Zydis). [1.3] Biological medicinal products [1.3.1] Biological medicinal products [1.3.1.2] Immunological products [1.5] Packaging |

[1.5.1] Primary packaging

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Freeze dried tablets (Zydis oral dispersible tablets)

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical