

# 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**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                              |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.13 ] Tablets<br>[ 1.2.1.17 ] Other non-sterile medicinal products<br>Freeze dried tablet (Zydis).<br><b>[ 1.3 ] Biological medicinal products</b><br>[ 1.3.1 ] Biological medicinal products<br>[ 1.3.1.2 ] Immunological products<br><b>[ 1.5 ] Packaging</b> |

[ 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