# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA(IMP) 14023

CATALENT UK SWINDON ZYDIS LIMITED

CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, UNITED KINGDOM

CATALENT UK SWINDON ZYDIS LIMITED, 1 GEORGE SQUARE, GLASGOW, G2 1AL, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)
Regulations 2004 [SI 2004/1031]

Confidential

30/10/2025

Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

## CATALENT UK SWINDON ZYDIS LIMITED, FRANKLAND ROAD, BLAGROVE, SWINDON, SN5 8RU, 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)

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Other non-sterile medicinal products freeze-dried, tablets, API coating using acoustic mixing for preparation of drug product intermediate

#### [ 1.3 ] Biological investigational medicinal products

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.2 ] Immunological products

Issue Date: 30 Oct 2025

# [ 1.5 ] Packaging

[1.5.1] Primary packaging

[ 1.5.1.13 ] Tablets

[ 1.5.1.15 ] Other non-sterile medicinal products

Specifically freeze dried tablets (Zydis oral dispersible tablets)

#### [ 1.6 ] Quality control testing

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

