

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

UK MIA 14017

2: Name of authorisation holder

DEXCEL PHARMA LIMITED

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

DEXCEL PHARMA LIMITED, 7 SOPWITH WAY, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8PB, UNITED KINGDOM

4: Legally registered address of authorisation holder

DEXCEL PHARMA LIMITED, 2ND FLOOR, BOURN, 1 MANOR HOUSE DRIVE, COVENTRY, CV1 2FX, UNITED KINGDOM

5: Scope of authorisation and dosage forms

DEXCEL PHARMA LIMITED, 2ND FLOOR, BOURN, 1 MANOR HOUSE DRIVE, COVENTRY, CV1 2FX, UNITED KINGDOM

6: Legal Basis of authorisation

ANNEX 1 and/ or ANNEX 2

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

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

8: Authorisation Date

Confidential

9: Annexes attached

24/11/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

DEXCEL PHARMA LIMITED, 7 SOPWITH WAY, DRAYTON FIELDS INDUSTRIAL ESTATE, DAVENTRY, NN11 8PB, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
[2.2] Batch certification of imported medicinal products
[2.2.2] Non-sterile products

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

DEXCEL PHARMA LIMITED, 2ND FLOOR, BOURN, 1 MANOR HOUSE DRIVE, COVENTRY, CV1 2FX, UNITED KINGDOM

Human 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 products
[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
[1.2.1.1] Capsules, hard shell
[1.2.2] Batch certification
Part 2 - IMPORTATION OF MEDICINAL PRODUCTS
[2.2] Batch certification of imported medicinal products
[2.2.2] Non-sterile products