

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 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 24/11/2025

9: Annexes attached 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