

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 50674

2: Name of authorisation holder BIOCON PHARMA UK LIMITED

3: Address(es) of manufacturing site(s) BIOCON PHARMA UK LIMITED, GROUND FLOOR, CAVENDISH HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW, UNITED KINGDOM

4: Legally registered address of authorisation holder MAWDSLEY-BROOKS & COMPANY LIMITED, UNIT 22, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT, UNITED KINGDOM

5: Scope of authorisation and dosage forms BIOCON PHARMA UK LIMITED, GROUND FLOOR, CAVENDISH HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW, 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 18/06/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BIOCON PHARMA UK LIMITED, GROUND FLOOR, CAVENDISH HOUSE, 369 BURNT OAK BROADWAY, EDGWARE, HA8 5AW, 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 [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised
[2.2.2] Non-sterile products

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MAWDSLEY-BROOKS & COMPANY LIMITED, UNIT 22, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging [1.5.2] Secondary packaging