

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, OFFICE 322, HAMILTON HOUSE, MABLEDON PLACE, LONDON, WC1H 9BB, 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, OFFICE 322, HAMILTON HOUSE, MABLEDON PLACE, LONDON, WC1H 9BB, 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 24/08/2026

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

BIOCON PHARMA UK LIMITED, OFFICE 322, HAMILTON HOUSE, MABLEDON PLACE, LONDON, WC1H 9BB, 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

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