

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 17901

2: Name of authorisation holder ASTRAZENECA UK LIMITED

3: Address(es) of manufacturing site(s) ASTRAZENECA UK LIMITED - MACCLESFIELD DEVELOPMENT, CHARTER WAY, SILK ROAD BUSINESS PARK, MACCLESFIELD, SK10 2NA, UNITED KINGDOM

4: Legally registered address of authorisation holder ASTRAZENECA UK LIMITED, 1 FRANCIS CRICK AVENUE, CAMBRIDGE BIOMEDICAL CAMPUS, CAMBRIDGE, CB2 0AA, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

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

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

8: Authorisation Date 31/03/2026

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ASTRAZENECA UK LIMITED - MACCLESFIELD DEVELOPMENT, CHARTER WAY, SILK ROAD BUSINESS PARK, MACCLESFIELD, SK10 2NA, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.3] Batch certification [1.2] Non-sterile investigational medicinal products [1.2.2] Batch certification [1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[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

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Hormones, cytotoxics/cytostatics/Importation of QP certified IMPs from a country on the approved' country for import list