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	14/07/2026
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

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[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

MHRA-GMDP MHRA-GMDP MHRA MHRA