Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 17901
2: Name of authorisation holder	ASTRAZENECA UK LIMITED
3: Address(es) of manufacturing site(s)	ASTRAZENECA UK LIMITED, 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	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	26/06/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

ASTRAZENECA UK LIMITED, CHARTER WAY, SILK ROAD BUSINESS PARK, MACCLESFIELD, SK10 2NA, 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

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.5] Solids and implants

Special Requirements

LHRH Agonist (Zoladex)

[1.1.1.6] Other aseptically prepared products

LHRH Agonist (Solids and Implants)

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.13] Tablets

Special Requirements

Antioestrogen (Nolvadex)

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing