

# 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** 09/10/2025

**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

|                                                                                                                                                                                                                                                                                                                                                            |
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| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                   |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                      |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.5 ] Solids and implants<br><b>Special Requirements</b><br>LHRH Agonist ( Zoladex)<br>[ 1.1.1.6 ] Other aseptically prepared products<br>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