Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK MIA 17901 Insp GMP/GDP/IMP 17901/10117-0043

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	ASTRAZENECA UK LIMITED
Site address	SILK ROAD BUSINESS PARK MACCLESFIELD SK10 2NA UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 17901 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/02/2020, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.

Digitally signed by Chirtoacă Iurie
Date: 2021.09.24 08:43:06 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate No: UK MIA 17901 Insp GMP/GDP/IMP 17901/10117-0043

Part 2

Human Medicinal Products

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:
Other
LHRH Agonist (Zoladex)

1.1.1.6 Other aseptically prepared products
LHRH Agonist (Solids and Implants)

1.1.2 Terminally sterilised (processing operations for the following dosage forms)

1.1.2.3 Small volume liquids

1.1.3 Batch Certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.1 Capsules, hard shell
1.2.1.5 Liquids for external use
1.2.1.6 Liquids for internal use
1.2.1.13 Tablets
Special Requirements:
Other
Antioestrogen (Nolvadex)

1.2.2 Batch Certification

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.1 Primary packaging

1.5.1.1 Capsules, hard shell
1.5.1.5 Liquids for external use
1.5.1.6 Liquids for internal use
1.5.1.8 Other solid dosage forms
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

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 products
2.2.1.2 Terminally sterilised products
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

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

Certificate No: UK MIA 17901 Insp GMP/GDP/IMP 17901/10117-0043

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 25/03/2020