Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 17901 Insp GMP 17901/10117-0054[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : ASTRAZENECA UK LIMITED

Site address : ASTRAZENECA UK LIMITED, CHARTER WAY, SILK ROAD BUSINESS PARK, MACCLESFIELD, SK10 2NA, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 17901 in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 25/04/2023 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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 valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

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
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
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

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

Restrictions or Remarks

THIS GMP CERTIFICATE IS APPLICABLE TO OPERATIONS CONDUCTED IN: PHARMACEUTICAL PRODUCTION BUILDING (PPB), GLOBAL PACKING CENTRE (GPC), SPECIAL TABLETS FACILITY (STF), PHARMACEUTICAL PRODUCTION BUILDING 2 (PPB2), COPOLYMER PRODUCTION LABORATORIES (CPL), STERILE PRODUCTS PLANT 3 (SPP3), STERILE PRODUCTS PLANT 4 (SPP4), STERILE PRODUCTS PLANT 5 (SPP5), QUALITY ASSURANCE BUILDING I / II (QAB), SITE ARCHIVE, WAREHOUSES.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
THIS GMP CERTIFICATE IS APPLICABLE TO OPERATIONS CONDUCTED IN: PHARMACEUTICAL PRODUCTION BUILDING (PPB), GLOBAL PACKING CENTRE (GPC), SPECIAL TABLETS FACILITY (STF), PHARMACEUTICAL PRODUCTION BUILDING 2 (PPB2), COPOLYMER PRODUCTION LABORATORIES (CPL), STERILE PRODUCTS PLANT 3 (SPP3), STERILE PRODUCTS PLANT 4 (SPP4), STERILE PRODUCTS PLANT 5 (SPP5), QUALITY ASSURANCE BUILDING I / II (QAB), SITE ARCHIVE, WAREHOUSES.				

29/01/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential