Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 530 Insp GMP/IMP 20864/14004-0036[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 : NORTON HEALTHCARE LIMITED T\A IVAX PHARMACEUTICALS UK

Site address : NORTON HEALTHCARE LIMITED T\A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 530 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 09/12/2024 , 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)

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products
Suspension and Emulsion Products

MHRA-GMDP MHRA

[1.1.3] Batch certification

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products
Monoclonal Antibodies

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products
Monoclonal Antibodies

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.4.2.3] Moist heat

[1.5] Packaging

[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

[1.6.4] Biological

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.3] Chemical/Physical

[2.1.4] Biological

[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

MHRA-GMDP MHRA

[2.2.3.8] Other biological medicinal products

Monoclonal Antibodies

[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 certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

09/12/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP