

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 29595 Insp GMP/GDP/IMP 29595/18244-0044[I]

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

Part 1

Issued following an inspection in accordance with :

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : PIRAMAL HEALTHCARE UK LIMITED

Site address : PIRAMAL HEALTHCARE UK LIMITED , WHALTON ROAD, MORPETH, NE61 3YA, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 29595 in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 23/12/2024 , 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 Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.1] Capsules, hard shell

[1.2.1.13] Tablets

Range of hormonal property tablets

[1.2.1.17] Other non-sterile medicinal products

Tablet/ medical device combination. Over encapsulation of a ranged dosage forms

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Packaging of a range of over encapsulated range of products. Packaging of tablet/ medical device combination

[1.5.2] Secondary packaging

[1.6] Quality control testing

[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

[2.1.2] 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

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Batch Certification of products imported into EU but not to the Piramal Morpeth site

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.

23/12/2024 Name and signature of the authorised person of the Competent Authority of United Kingdom
Confidential
Medicines and Healthcare products Regulatory Agency
Tel : Confidential