Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 49934 Insp IMP 49934/18458731-0002[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 : UPPERTON LIMITED

Site address : UPPERTON LIMITED, ALBERT EINSTEIN CENTRE, NOTTINGHAM SCIENCE AND TECHNOLOGY PARK, NOTTINGHAM, NG7 2TN, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 49934 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 27/07/2022 , 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

[1.2.1.6] Liquids for internal use

Substance with hormonal activity

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

Spray dried bulk intermediate pharmaceutical products for Oral, nasal and pulmonary administration.

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources.

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources.

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

GWP4202541 (API) in Acetone Solution

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Herbal

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological

Restrictions or Remarks

This certificate is granted on the basis that the company has committed to restrict packaging operations performed at this site for IMPs to Open-Label studies only.

MHRA-GMDP MHRA

12/07/2024	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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