Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 5866 Insp IMP 5866/21295-0018[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 : GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED

Site address : GLAXOSMITHKLINE RESEARCH & DEVELOPMENT LIMITED, THIRD AVENUE, HARLOW, CM19 5AW, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 5866 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 25/11/2021 , 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

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[1.2.2] Batch certification

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[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

[1.5.2] Secondary packaging

2. IMPORTATION OF MEDICINAL PRODUCTS

[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

[2.2.3.8] Other biological medicinal products

Synthetic Proteins

[2.3] Other Importation Activities

[2.3.4] Other

Authorised for Importation of QP certified IMPs from a country on the approved country for import li

Restrictions or Remarks

MIA GMP certification: the approval status is restricted to named patient supply to non-EU countries (no formal/commercial MIA activities undertaken on site).

MIA (IMP) GMP certification: the approval status is restricted to small-scale, phase 1 manufacture.

This was a focused remote inspection following a variation to add oversight process for IMP from listed countries of liquid and semisolid formulations.

10/02/2022	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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