Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 4757 Insp IMP 4757/15685-0040[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 : SIMBEC RESEARCH LIMITED

Site address : SIMBEC RESEARCH LIMITED, SIMBEC HOUSE, MERTHYR TYDFIL INDUSTRIAL PARK, MERTHYR TYDFIL, CF48 4DR, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 4757 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 03/11/2022 , 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

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.1] Large volume liquids

[1.1.1.4] Small volume liquids

[1.1.1.5] Solids and implants

[1.1.1.6] Other aseptically prepared products

Radiopharmaceuticals small and large volume liquids.Antibodies/other therapeutic proteins.Non live protein based vaccine

[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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.9] Pressurised preparations

[1.2.1.17] Other non-sterile medicinal products

Solutions for inhalation/nebulisation, Radiopharmaceuticals (solids, oral solutions, solutions for inhalation/nebulisation). Dry powder for nasal inhalation. Pressurised preparations, specifically radiolabelled products, Oral Powders

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Packaging of dry powder nasal sprays including hGH, Dilution of oral liquid vaccines containing genetically modified live bacteria.

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.2] Homeopathic products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.3] Chewing gums

[1.5.1.4] Impregnated matrices

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[1.5.1.17] Other non-sterile medicinal products

Solutions for inhalation/nebulisation, Radiopharmaceuticals (solids, oral solutions, solutions for inhalation/nebulisation). Dry powder for nasal inhalation. Pressurised preparations, specifically radiolabelled products, Oral Powders

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Radiopharmaceuticals/radionuclide generators/ Importation of QP certified IMPs from a country on the approved country for import list

Restrictions or Remarks

This was a focused remote inspection following a variation to add oversight process for IMP from listed countries.
Scope of QC testing limited to HPLC analysis.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
			Scope of QC testing limited to HPLC analysis.	

21/11/2022	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential