Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 4757
2: Name of authorisation holder	SIMBEC RESEARCH LIMITED
3: Address(es) of manufacturing site(s)	SIMBEC RESEARCH LIMITED, SIMBEC HOUSE, MERTHYR TYDFIL INDUSTRIAL PARK, MERTHYR TYDFIL, CF48 4DR, UNITED KINGDOM
4: Legally registered address of authorisation holder	SIMBEC RESEARCH LIMITED, SIMBEC HOUSE, MERTHYR TYDFIL INDUSTRIAL PARK, MERTHYR TYDFIL, CF48 4DR, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	04/03/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 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

[1.1.3] Batch certification

[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

[1.2.1.15] 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

[1.2.2] Batch certification

[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 investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.2] Homoeopathic 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

[1.5.1.15] 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

Part 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