Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 40211
2: Name of authorisation holder	SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED
3: Address(es) of manufacturing site(s)	SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM
4: Legally registered address of authorisation holder	SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, UNIT 10, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, 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	21/11/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, SCION HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, 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)

[1.1.1.2] Lyophilisates

Special Requirements

Cytotoxics

[1.1.1.4] Small volume liquids

Special Requirements

Cytotoxics

[1.1.1.6] Other aseptically prepared products

Suspensions

Special Requirements

Cytotoxics

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.15] Other non-sterile medicinal products

Lyophilisation of non-sterile active ingredients / excipients for use as starting materials in solid oral dosage manufacturing elsewhere

Special Requirements

Cytotoxics

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.4] Gene therapy products

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products

Plasmid, DNA, RNA. peptides. proteins and antibodies products. This list is only indicative of the product handled.

Special Requirements

Cytotoxics

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.3] Biological medicinal products

[2.2.3.4] Gene therapy products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing