Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 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 SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, UNIT B, LOGIE COURT, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, THE BRUCE BUILDING, CASTLE BUSINESS PARK, STIRLING, FK9 4TS, 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	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	11/02/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

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

Human 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 Products

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

[1.1.1.2] Lyophilisates

[1.1.1.4] Small volume liquids

Special Requirements

Cytotoxics

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.4] Gene therapy products

[1.3.1.5] Biotechnology products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.8] Other biological medicinal products

Plasmid, DNA, RNA, peptides, proteins and antibody products. This list is only indicative of he product handled. Special Requirements: Other Cytotoxics

Special Requirements

Cytotoxics

[1.4] Other products or manufacturing activity

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

[1.4.2.1] Filtration

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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, UNIT B, LOGIE COURT, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.8] Other biological medicinal products

Plasmid, DNA, RNA, peptides, proteins and antibody products.

Special Requirements

Cytotoxics

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, THE BRUCE BUILDING, CASTLE BUSINESS PARK, STIRLING, FK9 4TS, UNITED KINGDOM

Human 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 Products

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

[1.1.1.4] Small volume liquids

Special Requirements

Cytotoxics

[1.1.1.6] Other aseptically prepared products

Suspensions

Special Requirements

Cytotoxics

[1.1.3] Batch certification

[1.2] Non-sterile products

[1.2.2] Batch certification

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.2] Immunological products

[1.3.1.3] Cell therapy 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 antibody products. This list is only indicative of he product handled. Special Requirements: Other Cytotoxics

Special Requirements

Cytotoxics

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.4] Gene therapy products

[1.3.2.5] Biotechnology products

[1.3.2.8] Other biological medicinal products

Plasmid, DNA, RNA, peptides, proteins and antibody products. This list is only indicative of he product handled. Special Requirements: Other Cytotoxics

Special Requirements

Cytotoxics

[1.4] Other products or manufacturing activity

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

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.4] Biological

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