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 SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, SCION HOUSE, 3: Address(es) of manufacturing site(s) STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM SYMBIOSIS PHARMACEUTICAL SERVICES LIMITED, UNIT 10, SCION 4: Legally registered address of authorisation holder HOUSE, STIRLING UNIVERSITY INNOVATION PARK, STIRLING, FK9 4NF, UNITED KINGDOM 5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2 Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 6: Legal Basis of authorisation 2004/1031] 7: Name of responsible officer of the competent authority of the member state granting the Confidential manufacturing authorisation 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)	1
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	
	<i>N</i> .

[1.1.1.4] Small volume liquids
Special Requirements
[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
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