Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 10410
2: Name of authorisation holder	CORPUS NOSTRUM LIMITED
3: Address(es) of manufacturing site(s)	MANDEVILLE MEDICINES, STOKE MANDEVILLE HOSPITAL, MANDEVILLE ROAD, AYLESBURY, HP21 8AL, UNITED KINGDOM
4: Legally registered address of authorisation holder	CORPUS NOSTRUM LIMITED, UNIT 1, CARDINAL WAY, GODMANCHESTER, HUNTINGDON, CAMBRIDGESHIRE, PE29 2XN, 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	07/12/2020
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MANDEVILLE MEDICINES, STOKE MANDEVILLE HOSPITAL, MANDEVILLE ROAD, AYLESBURY, HP21 8AL, 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

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.2] Semi-solids

[1.1.2.3] Small volume liquids

[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

[1.2.1.11] Semi-solids

[1.2.1.12] Suppositories

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.3.1.6] Human or animal extracted products

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.4.2.2] Dry heat

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products