

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 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, ENTERPRISE HOUSE, UNIT 10, TRIANGLE BUSINESS PARK, QUILTERS WAY, STOKE MANDEVILLE, AYLESBURY, HP22 5BL, 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 | 05/11/2024 |
| 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

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| 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 activity

[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