

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 530 |
| 2: Name of authorisation holder | NORTON HEALTHCARE LIMITED |
| 3: Address(es) of manufacturing site(s) | NORTON HEALTHCARE LIMITED T/A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | NORTON HEALTHCARE LIMITED, RIDINGS POINT, WHISTLER DRIVE, CASTLEFORD, WF10 5HX, 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 | 19/03/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

NORTON HEALTHCARE LIMITED T/A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, UNITED KINGDOM

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| 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 |
| [1.1.1.6] Other aseptically prepared products Suspension and Emulsion Products |
| [1.1.3] Batch certification |
| [1.3] Biological medicinal products |
| [1.3.1] Biological medicinal products |

[1.3.1.8] Other biological medicinal products

Monoclonal Antibodies

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Monoclonal Antibodies

[1.4] Other products or manufacturing activity

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

[1.4.2.1] Filtration

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.2] Secondary packaging

[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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.1] Microbiological: sterility

[2.1.3] Chemical/Physical

[2.1.4] Biological

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.8] Other biological medicinal products

Monoclonal Antibodies

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing