Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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	01/11/2024
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

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