Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 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, ACCOUNTS PAYABLE DEPARTMENT, 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	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	25/02/2026
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

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 Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products

Suspensions and Emulsions

[1.1.3] Batch certification

MHRA-GMDP MHRA

[1.3] Biological investigational 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 investigational medicinal products or manufacturing activitiy

[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

MHRA-GMDP MHRA-GMDP MHRA MHRA