

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	30/10/2024
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

[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 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