

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 530
<b>2: Name of authorisation holder</b>	NORTON HEALTHCARE LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	NORTON HEALTHCARE LIMITED T/A IVAX PHARMACEUTICALS UK, ASTON LANE NORTH, WHITEHOUSE VALE INDUSTRIAL ESTATE, RUNCORN, WA7 3FA, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	NORTON HEALTHCARE LIMITED, ACCOUNTS PAYABLE DEPARTMENT, RIDINGS POINT, WHISTLER DRIVE, CASTLEFORD, WF10 5HX, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	02/05/2024
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 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 <b>[ 1.3 ] Biological investigational medicinal products</b>

- [ 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