

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 48101

**2: Name of authorisation holder** MAC RESEARCH LTD

MAC CLINICAL RESEARCH LIMITED - MAC CLINICAL RESEARCH  
FINANCE LTD, MONARCH HOUSE, WAKEFIELD ROAD, LEEDS,  
LS10 1DP, UNITED KINGDOM

**3: Address(es) of manufacturing site(s)**

MAC CLINICAL RESEARCH MANCHESTER-MAC CLINICAL  
RESEARCH FINANCE LIMITED, CITYLABS 1.0, NELSON STREET,  
MANCHESTER, M13 9NQ, UNITED KINGDOM

**4: Legally registered address of authorisation holder** MAC RESEARCH LTD, 19 PARK ROAD, LYTHAM ST. ANNES, FY8  
1PW, 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** 09/01/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**MAC CLINICAL RESEARCH LIMITED - MAC CLINICAL RESEARCH FINANCE LTD**, MONARCH HOUSE, WAKEFIELD ROAD,  
LEEDS, LS10 1DP, 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) [ 1.1.1.1 ] Large volume liquids

[ 1.1.1.4 ] Small volume liquids

[ 1.1.1.6 ] Other aseptically prepared products

Manipulation of previously formulated products e.g. cytotoxics and monoclonal antibodies, GMOs and vaccines.

[ 1.1.3 ] Batch certification

**[ 1.2 ] Non-sterile investigational medicinal products**

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.1 ] Capsules, hard shell

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.15 ] Other non-sterile medicinal products

Weighing and mixing of drug substance into individual subject dose containers

[ 1.2.2 ] Batch certification

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

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

[ 1.4.2.1 ] Filtration

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.2 ] Capsules, soft shell

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.13 ] Tablets

[ 1.5.1.15 ] Other non-sterile medicinal products

Weighing and mixing of drug substance into individual subject dose containers

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**MAC CLINICAL RESEARCH MANCHESTER-MAC CLINICAL RESEARCH FINANCE LIMITED, CITYLABS 1.0, NELSON STREET, MANCHESTER, M13 9NQ, UNITED KINGDOM**

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b>
<b>[ 1.5 ] Packaging</b>

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.2 ] Capsules, soft shell
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging