

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 48101
<b>2: Name of authorisation holder</b>	MAC RESEARCH LTD
<b>3: Address(es) of manufacturing site(s)</b>	MAC CLINICAL RESEARCH LIMITED - MAC CLINICAL RESEARCH FINANCE LTD, MONARCH HOUSE, WAKEFIELD ROAD, LEEDS, LS10 1DP, UNITED KINGDOM MAC CLINICAL RESEARCH MANCHESTER-MAC CLINICAL RESEARCH FINANCE LIMITED, CITYLABS 1.0, NELSON STREET, MANCHESTER, M13 9NQ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	MAC RESEARCH LTD, 19 PARK ROAD, LYTHAM ST. ANNES, FY8 1PW, 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>	14/10/2024
<b>9: Annexes attached</b>	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