Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 48101
2: Name of authorisation holder	MAC RESEARCH LTD
3: Address(es) of manufacturing site(s)	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
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	01/07/2026
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)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

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

[1.1.1.1] Large volume liquids

MHRA-GMDP

[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. Combination Intermediate IMP and microneedle drug delivery matrix.

[1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activitiy

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

[1.4.2.1] Filtration

[1.5] 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. Combination Intermediate IMP and microneedle drug delivery matrix.

[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)

MHRA-GMDP MHRA-GMDP MHRA

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.8] Other solid dosage forms

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

MHRA-GMDP