Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 21761
2: Name of authorisation holder	UNIVERSITY OF BIRMINGHAM
3: Address(es) of manufacturing site(s)	UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM UNIVERSITY OF BIRMINGHAM, MICROBIOME TREATMENT CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM
4: Legally registered address of authorisation holder	UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, 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	30/05/2025
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UNIVERSITY OF BIRMINGHAM, CELL THERAPY FACILITY, ADVANCED THERAPIES FACILITY, WOLFSON DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.5] Packaging

[1.5.2] Secondary packaging

MHRA-GMDP

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UNIVERSITY OF BIRMINGHAM, MICROBIOME TREATMENT CENTRE, VINCENT DRIVE, EDGBASTON, BIRMINGHAM, B15 2TT, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Faecal Microbiome

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Faecal Microbiome

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

Storage of products in cryobags and cryiovials. Extraction of faecal microbiome from human faeces

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.6] Liquids for internal use

[1.5.1.15] Other non-sterile medicinal products

Faecal Microbiome

[1.5.2] Secondary packaging

MHRA-GMDP MHRA-GMDP MHRA MHRA