

# Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA(IMP) 59749 Insp IMP 59749/37415393-0001[I]

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

### Part 1

Issued following an inspection in accordance with :

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : 4BASEBIO UK LTD

Site address : 4BASEBIO UK LTD, UNIT 12 & UNIT 18, MERIDIAN, BUCKINGWAY BUSINESS PARK, ANDERSON ROAD, SWAVESEY, CAMBRIDGE, CB24 4AE, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA(IMP) 59749 in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 04/03/2025 , it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- (1) *Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- (2) *These requirements fulfil the GMP recommendations of WHO.*

### Part 2

#### Human Investigational Medicinal Products

#### 1. MANUFACTURING OPERATIONS

##### [ 1.3 ] Biological investigational medicinal products

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.8 ] Other biological medicinal products

ATMP Manufacture- a) Critical Starting Material- CDMO Manufacturing of Synthetic DNA template for IMP drug substance manufacturing b) Drug Substance- CDMO Manufacturing of Synthetic DNA for IMP drug product

31/03/2025 Name and signature of the authorised person of the Competent Authority of United Kingdom  
Confidential  
Medicines and Healthcare products Regulatory Agency  
Tel : Confidential

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