

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 62229 |
| 2: Name of authorisation holder | ACCELERATE NEWCO LIMITED |
| 3: Address(es) of manufacturing site(s) | ACCELERATE NEWCO LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder | ACCELERATE NEWCO LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, 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 | 27/03/2026 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

ACCELERATE NEWCO LIMITED, STEPHENSON BUILDING, THE SCIENCE PARK, KEELE, NEWCASTLE, ST5 5SP, UNITED KINGDOM

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| Human Investigational Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal Products [1.1.1] Aseptically prepared (processing operations for the following dosage forms) [1.1.1.4] Small volume liquids [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.6] Liquids for internal use |

- [1.2.1.15] Other non-sterile medicinal products
Manufacture of low bioburden bulk drug substance solutions.

[1.3] Biological investigational medicinal products

- [1.3.1] Biological medicinal products
 - [1.3.1.2] Immunological products
 - [1.3.1.4] Gene therapy products
 - [1.3.1.5] Biotechnology products
 - [1.3.1.8] Other biological medicinal products
Antibodies, antibody conjugates Live microbial products; Therapeutic Virus; Plant extracted materials.
- [1.3.2] Batch certification
 - [1.3.2.2] Immunological products
 - [1.3.2.4] Gene therapy products
 - [1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activity

- [1.4.2] Sterilisation of active substances/excipients/finished products:
 - [1.4.2.1] Filtration
 - [1.4.2.3] Moist heat

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical
- [1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

- [2.1.2] Microbiological: non-sterility
- [2.1.3] Chemical/Physical
- [2.1.4] Biological

[2.2] Batch certification of imported medicinal products

- [2.2.1] Sterile Products
 - [2.2.1.1] Aseptically prepared
 - [2.2.1.2] Terminally sterilised
- [2.2.2] Non-sterile products
- [2.2.3] Biological medicinal products
 - [2.2.3.2] Immunological products
 - [2.2.3.3] Cell therapy products
 - [2.2.3.4] Gene therapy products
 - [2.2.3.5] Biotechnology products
 - [2.2.3.6] Human or animal extracted products
 - [2.2.3.8] Other biological medicinal products
Antibodies, antibody conjugates Live microbial products; Therapeutic Virus; Plant extracted materials.