

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|   |   |
|---|---|
| <b>1: Authorisation Number</b>  | UK MIA 34424  |
| <b>2: Name of authorisation holder</b>  | KEY PHARMACEUTICALS LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | KEY PHARMACEUTICALS LIMITED, GALEN HOUSE, 83 HIGH STREET, SOMERSHAM, HUNTINGDON, PE28 3JB, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | KEY PHARMACEUTICALS LIMITED, 18 OXLEASOW ROAD, REDDITCH, B98 0RE, UNITED KINGDOM                          |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2   |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)                                      |
| <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>  | 19/11/2024  |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**KEY PHARMACEUTICALS LIMITED**, GALEN HOUSE, 83 HIGH STREET, SOMERSHAM, HUNTINGDON, PE28 3JB, UNITED KINGDOM

|  |
|--|
| Human Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)  |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.2 ] Batch certification<br>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.2 ] Non-sterile products<br><b>[ 2.3 ] Other Importation Activities</b> |

[ 2.3.4 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)  
Placing manufacturing orders on non EU manufacturing sites, for delivery to

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA