Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 34424
2: Name of authorisation holder	KEY PHARMACEUTICALS LIMITED
3: Address(es) of manufacturing site(s)	KEY PHARMACEUTICALS LIMITED, GALEN HOUSE, 83 HIGH STREET, SOMERSHAM, HUNTINGDON, PE28 3JB, UNITED KINGDOM KEY PHARMACEUTICALS LIMITED, 18 OXLEASOW ROAD, REDDITCH, B98 0RE, UNITED KINGDOM
4: Legally registered address of authorisation holder	KEY PHARMACEUTICALS LIMITED, 18 OXLEASOW ROAD, REDDITCH, B98 0RE, UNITED KINGDOM
5: Scope of authorisation and dosage forms	ANNEX 1 and/ or ANNEX 2
6: Legal Basis of authorisation	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	29/04/2026
9: Annexes attached	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) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.2] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

MHRA-GMDP MHRA

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[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

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

KEY PHARMACEUTICALS LIMITED, 18 OXLEASOW ROAD, REDDITCH, B98 0RE, UNITED KINGDOM

Human Medicinal Products

Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.2] Batch certification

MHRA-GMDP MHRA-GMDP MHRA MHRA