Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 25258
2: Name of authorisation holder	GLENMARK PHARMACEUTICALS EUROPE LIMITED
3: Address(es) of manufacturing site(s)	GLENMARK PHARMACEUTICALS EUROPE LIMITED , BUILDING 2, CROXLEY GREEN BUSINESS PARK, MARLINS MEADOW, WATFORD, WD18 8YA, UNITED KINGDOM
4: Legally registered address of authorisation holder	GLENMARK PHARMACEUTICALS EUROPE LIMITED, LAXMI HOUSE, 2-B DRAYCOTT AVENUE, KENTON, HARROW, HA3 0BU, 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	11/06/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

GLENMARK PHARMACEUTICALS EUROPE LIMITED , BUILDING 2, CROXLEY GREEN BUSINESS PARK, MARLINS MEADOW, WATFORD, WD18 8YA, 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

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products