Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)

UK MIA 25258

GLENMARK PHARMACEUTICALS EUROPE LIMITED

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

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

- 8: Authorisation Date
- 9: Annexes attached

GLENMARK PHARMACEUTICALS EUROPE LIMITED, LAXMI HOUSE, 2-B DRAYCOTT AVENUE, KENTON, HARROW, HA3 0BU, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

Confidential

11/06/2024

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