

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 51841

2: Name of authorisation holder GMP MANUFACTURING LTD

3: Address(es) of manufacturing site(s) GMP MANUFACTURING LTD, PARK ROYAL HOUSE AND MARFLEET HOUSE, VALLETTA STREET, HULL, HU9 5NP, UNITED KINGDOM

4: Legally registered address of authorisation holder GMP MANUFACTURING LTD, MARFLEET HOUSE, VALLETTA STREET, HULL, HU9 5NP, 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 21/01/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

GMP MANUFACTURING LTD, PARK ROYAL HOUSE AND MARFLEET HOUSE, VALLETTA STREET, HULL, HU9 5NP, 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 [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.5] Liquids for external use [1.2.1.11] Semi-solids [1.2.2] Batch certification [1.5] Packaging [1.5.1] Primary packaging

[1.5.1.5] Liquids for external use

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

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