

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 32515

2: Name of authorisation holder STERLING PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s) STERLING PHARMACEUTICALS LIMITED, 288 UPPER BALSALL HEATH ROAD, BIRMINGHAM, B12 9DR, UNITED KINGDOM

4: Legally registered address of authorisation holder STERLING PHARMACEUTICALS LIMITED, 288 UPPER BALSALL HEATH ROAD, BIRMINGHAM, B12 9DR, 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 03/07/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

STERLING PHARMACEUTICALS LIMITED, 288 UPPER BALSALL HEATH ROAD, BIRMINGHAM, B12 9DR, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
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 [1.2.1.6] Liquids for internal 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

[1.5.1.6] Liquids for internal use

[1.5.1.11] Semi-solids

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical