

# 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** 21/11/2025

**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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 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 <b>[ 1.5 ] Packaging</b> [ 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