# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|---|
| **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** | 21/08/2024 |
| **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

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|---|
| 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