

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 17509

**2: Name of authorisation holder** ESTEVE PHARMACEUTICALS LTD

**3: Address(es) of manufacturing site(s)** ESTEVE PHARMACEUTICALS LTD, THE GRANARY, THE COURTYARD BARNs, CHOKE LANE, COOKHAM DEAN, MAIDENHEAD, SL6 6PT, UNITED KINGDOM

**4: Legally registered address of authorisation holder** ESTEVE PHARMACEUTICALS LTD, THE GRANARY, THE COURTYARD BARNs, CHOKE LANE, COOKHAM DEAN, MAIDENHEAD, SL6 6PT, 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** 09/08/2024

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**ESTEVE PHARMACEUTICALS LTD**, THE GRANARY, THE COURTYARD BARNs, CHOKE LANE, COOKHAM DEAN, MAIDENHEAD, SL6 6PT, UNITED KINGDOM

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|---|
| Human Medicinal Products  |
| Authorised Operations   |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.2 ] Batch certification<br><b>Part 2 - IMPORTATION OF MEDICINAL PRODUCTS</b> |

**[ 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