

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

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