

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 56021

**2: Name of authorisation holder** TORBAY PHARMACEUTICALS LIMITED

**3: Address(es) of manufacturing site(s)** TORBAY PHARMACEUTICALS LIMITED, TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM

**4: Legally registered address of authorisation holder** TORBAY PHARMACEUTICALS LIMITED, TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM

**5: Scope of authorisation and dosage forms** ANNEX 1 and/ or ANNEX 2

**6: Legal Basis of authorisation** Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

**7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation** Confidential

**8: Authorisation Date** 31/12/2025

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

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**TORBAY PHARMACEUTICALS LIMITED**, TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms) [ 1.1.2.1 ] Large volume liquids [ 1.1.2.3 ] Small volume liquids [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal 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

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

- [ 1.4.1 ] Manufacture of:
  - [ 1.4.1.1 ] Herbal products
- [ 1.4.2 ] Sterilisation of active substances/excipients/finished products:
  - [ 1.4.2.3 ] Moist heat

**[ 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

**[ 1.6 ] Quality control testing**

- [ 1.6.1 ] Microbiological: sterility
- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

- [ 2.1.1 ] Microbiological: sterility
- [ 2.1.2 ] Microbiological: non-sterility
- [ 2.1.3 ] Chemical/Physical

**[ 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

**[ 2.3 ] Other Importation Activities**

- [ 2.3.4 ] Other
  - Packaging and overlabelling