

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number**

UK MIA 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**

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**

31/12/2025

**9: Annexes attached**

Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

- [ 1.1.2 ] 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

##### [ 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

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

[ 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

[ 1.5.2 ] Secondary packaging

**[ 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 ] Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)  
Packaging and overlabelling