

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)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Investigational Medicinal 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 investigational medicinal 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 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