

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 56021
<b>2: Name of authorisation holder</b>	TORBAY PHARMACEUTICALS LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	TORBAY PHARMACEUTICALS LIMITED, TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	TORBAY PHARMACEUTICALS LIMITED, 13TH FLOOR NUMBER ONE SPINNINGFIELDS, 1 HARDMAN SQUARE, MANCHESTER, M3 3EB, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	10/05/2024
<b>9: Annexes attached</b>	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