



Medicines & Healthcare products
Regulatory Agency



MHRA

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Sally Andrews
TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
TORBAY PHARMACEUTICALS
KEMMINGS CLOSE
PAIGNTON
TQ4 7TW
UNITED KINGDOM



MIA(IMP) MIA(IMP) 13079
NUMBER:

Version: 32

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1A

1. Authorisation Number

MIA(IMP) Number: MIA(IMP) 13079

2. Name of Authorisation Holder

TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST

3. Trading Style

TORBAY PHARMACEUTICALS

4. Address(es) of manufacturing/importing site(s)

(All authorised sites should be listed if not covered by separate licences)

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
11009752	TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST	TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM

5. Legally registered address of Authorisation Holder

HEAD OFFICE, HENGRAVE HOUSE, TORBAY HOSPITAL, TORQUAY, TQ2 7AA, UNITED KINGDOM

6. Scope of authorisation and dosage forms

See Annex 2

7. Legal basis of authorisation

See Section 1B of authorisation.



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8. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

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SECTION 1A (continued)

9. Date 27/11/2020

10. Annexes attached

Annex 2

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)



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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1B

1. This authorisation is granted in accordance with the provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] which implement Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001.
2. It permits the authorisation holder named on page 1 of Section 1 of the authorisation to manufacture, assemble and/or import investigational medicinal products for human use in accordance with Regulation 41 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] (as detailed in section 3 of this authorisation) and is subject to the provisions identified on page 2 of Section 1 of this authorisation.
3. In this document a Manufacturers Authorisation for Investigational Medicinal Products may be referred to as MIA(IMP) and the Medicines and Healthcare products Regulatory Agency (acting on behalf of the Licensing Authority as defined in Regulation 6 of The Human Medicines Regulations 2012 (SI 2012/1916) may be referred to as MHRA.
4. The authorisation holder must inform the MHRA, in advance, of any change to the details submitted by him and/or included in this authorisation. All changes must be approved by the MHRA to have effect. If the business should change hands, the company or person taking over the business will have to obtain a new authorisation before commencing the manufacture, assembly or importation of investigational medicinal products.

Attention is drawn to the structure of this authorisation (as detailed on page 4 of Section 1) and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.



SECTION 1B (continued)

5. Authorisation Structure

This authorisation is divided into three sections.

- (a) Section 1 (this section) identifies the authorisation holder and the responsible officer for the issue of the authorisation. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.
 - (b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.
 - (c) Section 3 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.
 - (d) The authorisation holder is required to attach to his authorisation any replacement pages issued by MHRA and to mark or destroy superseded pages as to render them invalid.
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6. Provisions

- a) The provisions of Schedule 7 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] shall apply to the authorisation. For manufacture and/or assembly Parts 1 and 2 of Schedule 7 apply and for importation Parts 1 and 3 of Schedule 7 apply in accordance with Regulation 40(4) of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] subject to Regulation 38(2).



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
10/05/2004	Initial application
13/04/2007	Variation 1. To update personnel. 2. Add new site Applied Analysis Ltd.
26/08/2008	Internal variation to amend licence regarding personnel.
26/09/2008	Change of company name from South Devon Healthcare NHS Trust to South Devon Healthcare NHS Foundation Trust.
26/11/2008	Update licence to EUDRA GMP format
16/12/2008	Variation to amend licence, amend site 123417 from contract laboratory to QC testing, remove contract laboratory Applied Analysis and add FDAS and Molecular identification Services Unit as contract laboratories.
31/12/2008	Internal variation to amend contract lab functions for site id 89689, also to amend Mr Bendell to QP & PM for this site.
21/05/2009	Variation to add additional Contract Laboratory Reading Scientific Services Ltd (Site 38651)
27/09/2010	Variation to add Mr Mark Andrews as an additional QP.
01/09/2011	Variation to remove Miss Joanna Beaufoy from the licence as she has left the company, remove site 27841 (Molecular Identification Services Unit) and remove section 1.1.2.5 (Other terminally sterilised prepared products) from site 3598
18/04/2012	Variation to remove Mr M Santillo as Quality Controller and replace with Mr M Andrews, retain Mr santillo as QP IMP. remove Ms RJ Bell as QP IMP.
11/10/2013	Variation to remove Mr Phil Bendell as PM and QP and add Ms Janet Draper as PM, sites 3598 & 90482
17/01/2014	Variation to add Contract Laboratory JC Analytical.
16/04/2014	Variation to remove Ms Janet Draper as Head of Production and to add Mr David Hine as Head of Production.



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27/10/2014	Variation to add a new Quality Control Laboratory testing site
19/12/2014	Variation to site 3598: add Mr A Bosley as QP.
05/05/2015	Variation to Add a new Storage and Handling site. Wilkins Drive, Paignton, TQ4 7FG: site 11009752 . Wilkins Drive . Site number 11009752 to add microbiological testing (sterility) to the QC testing activity undertaken at the site.
19/08/2015	Variation to delete Mr Mark Santillo (QP) from site 3598
01/12/2015	Variation: Remove Site 90482 (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST). Add Trading style as Torbay Pharmaceuticals. Change name of Site 3598 to Torbay and South Devon NHS Foundation Trust. Change Address Line 1 from Pharmaceutical Manufacturing Unit to Torbay Pharmaceuticals. Site 11009752: Remove Mr Ashley Noyce as SC. Add Mr Mark Christopher Colin Andrews as a QP and QC. Retain as SC. Add Mr David Hine as a PM. Add Mr Alexander Bosley as a QP. Add Mrs Sally Andrews as a TQP. Site 3598: Update Mrs Sally Andrews as a TQP. Update Mr Mark Christopher Colin Andrews as SC. Add / Update Contract Laboratories (JC Analytical Ltd, Food & Drug Analytical Service Ltd, Scottish Blood Transfusion Service).
21/09/2016	Variation: Add Secondary Packaging (Site 11009752)
28/09/2016	Site 11009752 - replace Mark Andrews with Mr Alex Bosley as QC (but keep both as QP) - add Mr Julian Smith (127165) as TQP Site 3598 - replace Mark Andrews with Mr Alex Bosley as QC (but keep both as QP) - add Mr Julian Smith (127165) as TQP
28/11/2016	Variation: (Site 11009752) Add Manufacture site type and functions (small volume liquids)
03/01/2017	Variation: Remove Contract Laboratory (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST)
06/02/2017	Variation: Remove Contract Laboratory, Storage & Handling and Dry Heat & Gamma Irradiation (Site 11009752) Add Manufacturing, Large volume liquids (Site 11009752) Remove Storage & Handling and QC testing (Site 3598)
31/08/2017	variation: - delete site 3598 from the licence - add Helvic Laboratories as a contract Lab - delete Peter Adams (QP) from site 11009752
03/09/2018	Variation (site 11009752): Add importation; Replace the Head of Production with Mrs Adrienne Kennedy



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26/07/2019	Variation to add Reading Scientific Services Ltd (site 18816940) as a Contract Lab
23/01/2020	Variation -Remove Alex Bosley as QC. Add Alison Webber and Rebecca Smith as QC. Correct Julian Smith role to QP. Add Batch Certification, Primary Packaging - Liquids for external use, Liquids for internal use, Non-Sterile Products Batch Certification, Sterile Products Batch Certification
27/02/2020	Variation to add Miss Gabrielle Kelsey as PM to site 11009752. To add Mr Jamie Hoyle as PM to site 11009752
20/04/2020	Variation (site 11009752) to: -Remove Mrs Adrienne Kennedy & Mr David Hine as PM's. -Add Mr Gareth Price as QP & QC. -Add Mr Ross Walker as QP.
24/04/2020	Variation to add site 19259723
27/11/2020	Variation (site 11009752) to remove Mr Gareth Price as QP & QC & add Mr Ross Walker as QC.



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The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
ADDRESS:	TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM
MHRA SITE NUMBER:	11009752

Type of products handled

Human Investigational Medicinal Products for phase I, II, III clinical trials (optional)
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Authorised operations

Manufacturing Operations of Investigational Medicinal Products (according to Part 1)	Authorised
Importation of Investigational Medicinal Products (according to Part 2)	Authorised



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ANNEX 2 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	Sterile Investigational Medicinal Products	Manufacture
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
	1.1.1.1 Large volume liquids	Not Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids	Not Authorised
	1.1.1.4 Small volume liquids	Not Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products	Not Authorised



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1.1.2	<i>Terminally Sterilised (processing operations for the following dosage forms)</i>	Manufacture
	1.1.2.1 Large volume liquids	Authorised
	1.1.2.2 Semi-solids	Not Authorised
	1.1.2.3 Small volume liquids	Authorised
	1.1.2.4 Solids and implants	Not Authorised
	1.1.2.5 Other terminally sterilised prepared products	Not Authorised
1.1.3	<i>Batch certification</i>	Authorised



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1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	<i>Non-Sterile Products (processing operations for the following dosage forms)</i>	
	1.2.1.1 Capsules, hard shell	Not Authorised
	1.2.1.2 Capsules, soft shell	Not Authorised
	1.2.1.3 Chewing gums	Not Authorised
	1.2.1.4 Impregnated matrices	Not Authorised
	1.2.1.5 Liquids for external use	Authorised
	1.2.1.6 Liquids for internal use	Authorised
	1.2.1.7 Medicinal gases	Not Authorised
	1.2.1.8 Other solid dosage forms	Not Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	Not Authorised



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	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products	Not Authorised
1.2.2	Batch certification	Authorised



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1.3	Biological investigational medicinal products	Manufacture
1.3.1	<i>Biological medicinal products (list of product types)</i>	
	1.3.1.1 Blood products	Not Authorised
	1.3.1.2 Immunological products	Not Authorised
	1.3.1.3 Cell therapy products	Not Authorised
	1.3.1.4 Gene therapy products	Not Authorised
	1.3.1.5 Biotechnology products	Not Authorised
	1.3.1.6 Human or animal extracted products	Not Authorised
	1.3.1.7 Tissue Engineered Products	Not Authorised
	1.3.1.8 Other biological medicinal products	Not Authorised
1.3.2	<i>Batch certification</i>	
	1.3.2.1 Blood products	Not Authorised
	1.3.2.2 Immunological products	Not Authorised
	1.3.2.3 Cell therapy products	Not Authorised
	1.3.2.4 Gene therapy products	Not Authorised



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	1.3.2.5 Biotechnology products	Not Authorised
	1.3.2.6 Human or animal extracted products	Not Authorised
	1.3.2.7 Tissue Engineered Products	Not Authorised
	1.3.2.8 Other biological medicinal products	Not Authorised



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1.4	<i>Other investigational medicinal products or manufacturing activity</i> (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	Manufacture
1.4.1	Manufacture of:	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Other	Not Authorised
1.4.2	Sterilisation of active substances/excipients/finished products:	
	1.4.2.1 Filtration	Not Authorised
	1.4.2.2 Dry heat	Not Authorised
	1.4.2.3 Moist heat	Authorised
	1.4.2.4 Chemical	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
1.4.3	Others	Not Authorised



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1.5	Packaging	Packaging
1.5.1	Primary packing	
	1.5.1.1 Capsules, hard shell	Not Authorised
	1.5.1.2 Capsules, soft shell	Not Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Authorised
	1.5.1.6 Liquids for internal use	Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Not Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Not Authorised



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	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	Secondary packing	Authorised



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1.6	Quality control testing	
	1.6.1 Microbiological: sterility	Authorised
	1.6.2 Microbiological: non-sterility	Authorised
	1.6.3 Chemical/Physical	Authorised
	1.6.4 Biological	Not Authorised

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:



ANNEX 2 – SITE INFORMATION (continued)

Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS

- authorised importation activities without manufacturing activity
- authorised importation activities include storage and distribution unless informed to the contrary

2.1	Quality control testing	Import
	2.1.1 Microbiological: sterility	Authorised
	2.1.2 Microbiological: non-sterility	Authorised
	2.1.3 Chemical/Physical	Authorised
	2.1.4 Biological	Not Authorised
2.2	Batch certification of imported medicinal products	
2.2.1	Sterile Products	
	2.2.1.1 Aseptically prepared	Authorised
	2.2.1.2 Terminally sterilised	Authorised
2.2.2	Non-sterile products	Authorised
2.2.3	Biological medicinal products	
	2.2.3.1 Blood products	Not Authorised
	2.2.3.2 Immunological products	Not Authorised
	2.2.3.3 Cell therapy products	Not Authorised



	2.2.3.4 Gene therapy products	Not Authorised
	2.2.3.5 Biotechnology products	Not Authorised
	2.2.3.6 Human or animal extracted products	Not Authorised
	2.2.3.7 Tissue Engineered Products	Not Authorised
	2.2.3.8 Other biological medicinal products	Not Authorised
2.3	Other Importation Activities	
	2.3.1 Site of Physical Importation	Not Authorised
	2.3.2 Importation of Intermediate which undergoes further processing	Not Authorised
	2.3.3 Biological Active Substances	Not Authorised
	2.3.4 Other Packaging and overlabelling	Authorised

Any restrictions or clarifying remarks related to the scope of these importing operations:



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ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

<u>Person Number</u>	<u>Name</u>	<u>Personnel Type</u>			
		<u>QP</u>	<u>TQP</u>	<u>PM</u>	<u>QC</u>
1471059	Dr Alison Webber	No	No	No	Yes
20177946	Miss Rebecca Smith	No	No	No	Yes
20260183	Mr Jamie Hoyle	No	No	Yes	No
127165	Dr Julian C Smith	Yes	No	No	No
1183749	Sally Andrews	No	Yes	No	No
1284910	Mr Ross Walker	Yes	No	No	Yes
1282631	Mr Alex Bosley	Yes	No	No	No
376579	Mr Mark Christopher Colin Andrews	Yes	No	No	No
20260179	Miss Gabrielle Kelsey	No	No	Yes	No

Key to Roles:

QP – Qualified Person
TQP – Transitional Qualified Person
PM – Production Manager/Supervisor
QC – Person responsible for Quality Control



ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
37653	JC ANALYTICAL LIMITED	UNIT A, FLORENCE ROAD BUSINESS PARK, KELLY BRAY, CALLINGTON, PL17 8EX, UNITED KINGDOM
38651	READING SCIENTIFIC SERVICES LIMITED	READING SCIENCE CENTRE, WHITEKNIGHTS CAMPUS, PEPPER LANE, READING, RG6 6LA, UNITED KINGDOM
89536	FOOD & DRUG ANALYTICAL SERVICE LIMITED	BIOCITY, PENNYFOOT STREET, NOTTINGHAM, NG1 1GF, UNITED KINGDOM
383461	SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE	CASTLELAW BUILDING, PENTLANDS SCIENCE PARK, BUSH LOAN, PENICUIK, EH26 0PZ, UNITED KINGDOM
2968688	HELVIC LIMITED	UNIT E4, TRENTAM BUSINESS QUARTER, BELLRINGER ROAD, TRENTAM, STOKE- ON-TRENT, ST4 8GB, UNITED KINGDOM
18816940	READING SCIENTIFIC SERVICES LIMITED	2-3 MILLARS BUSINESS CENTRE, FISHPONDS CLOSE, WOKINGHAM, RG41 2TZ, UNITED KINGDOM
19259723	TEPNEL PHARMA SERVICES LIMITED	APPLETON PLACE, APPLETON PARKWAY, LIVINGSTON, EH54 7EZ, UNITED KINGDOM