



Medicines & Healthcare products
Regulatory Agency



MHRA

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United Kingdom

gov.uk/mhra

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



MIA NUMBER: MIA 13079

Version: 42

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

Manufacturer's/Importer's Licence

SECTION 1A

1. Licence Number

MIA Number: MIA 13079

2. Name of Licence 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 Licence Holder

HEAD OFFICE, HENGRAVE HOUSE, TORBAY HOSPITAL, TORQUAY, TQ2 7AA, UNITED KINGDOM
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6. Scope of licence and dosage form

See ANNEX 1

7. Legal basis of licence

See Section 1B of licence.

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 1

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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SECTION 1B

1. This licence is granted in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.
2. It authorises the processes of manufacture and/or assembly and/or importation of medicinal products of the description or general classification at the premises specified and in accordance with the particulars set out in Section 3 by the licence holder named. All manufacturing and/or assembly and/or importation operations in respect of those products for which a product licence is required shall be conducted so as to ensure that the products shall conform to the standards of strength, quality and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured and/or assembled and/or imported or the specification under which the products are sold or supplied.

In relation to such products the licence holder shall either:

- a) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with such specification any tests of the strength, quality or purity as required by that specification or,
 - b) make arrangements with a person approved by the Licensing Authority for such tests to be carried out on his behalf by that person and
 - c) make arrangements for a qualified person to be available at all times for the purpose of checking that each batch of medicinal products has been manufactured and assembled in accordance with the appropriate provisions and to certify accordingly in a register.
3. The operations referred to in Section 3 shall be undertaken by the personnel named therein or by such other person as may be approved by the Licensing Authority.

Attention is drawn to the structure of this licence (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 licence is using it as evidence to a third party in support of claims to carry out those operations and activities to which this licence applies on premises and using personnel covered by this licence.



SECTION 1B (continued)

4. The licence holder's arrangement for:
 - a) identification and storage of materials and ingredients before and during manufacture and for the storage of medicinal products after manufacture and assembly;
 - b) ensuring a satisfactory turnover of stock of medicinal products;
 - c) maintaining records of production, of analytical and other testing procedures and a register certified by a qualified person for each batch of proprietary medicines manufactured;
 - d) keeping reference samples of materials used in the manufacture of any medicinal products shall be in accordance with the particulars contained in or furnished in connection with the application of this licence, or shall be in accordance with such other arrangements as may from time to time be approved by the Licensing Authority
5. The licence holder must inform the Licensing Authority in advance of any change to the details submitted or included in this licence. All changes must be approved by the Licensing Authority prior to becoming effective. This includes any changes to named premises, persons, operations processes or structural alterations. If the business should change hands the new company or person must obtain a new licence prior to commencing operations. The manufacture and/or assembly and/or importation of any proprietary medicinal product pursuant to this licence shall not commence until the approval of the Licensing Authority has been given on the appropriate product licence to the site(s) named on this licence being used for the manufacture of that product.
6. A licence may be suspended if any fees are not paid in full as they fall due.
7. The Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).
8. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.
9. Licence Structure

This Licence is divided into three sections.

 - (a) Section 1 (this section) identifies the licence holder and holds the authorising name for the issue of the licence. This section would not usually be replaced during routine variations of the licence unless the licence holder details are varied.
 - (b) Section 2 lists variations to the licence. A replacement section 2 will be issued each time the licence is varied.
 - (c) Section 3 contains the details relating to each site named on the licence. 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 licence holder is required to attach to his licence any replacement pages issued by the Licensing Authority and to mark or destroy superseded pages as to render them invalid.



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The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's/Importer's Licence

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
15/11/1996	Initial application
25/01/1999	Renewal
11/10/2001	Renewal with changes to change licence holder contact to Mr Bendell, update telephone and fax numbers, site 8829 - delete As, add Ap, Dr, Cm and Xm and delete Mr Bendell and Mr Costley as QP's. Site 7813 - change site from Manufacturing and Assembly to Analytical Testing site - codes Lc and Lm.
15/11/2002	Variation to add additional AT sites to licence.
05/08/2003	Variation to update Licence Holders address and replace Dr PS Adams with Mr P Bendell as a QP on licence.
17/02/2007	Variation to add Mr M Santillo and Miss J Beaufoy as additional QP's, also Mr M Santillo as QC, remove Dr R F Haines-Nutt as QC and QP, and add an additional site: Applied Analysis.
11/03/2007	Internal variation to amend licence regarding sterile products.
06/06/2007	Internal variation to amend licence.
26/09/2008	Change of company name from South Devon Healthcare NHS Trust to South Devon Healthcare NHS Foundation Trust.
26/10/2008	Update licence to EUDRA GMP format.
26/10/2008	Update licence to EUDRA GMP format.
03/12/2008	Further update EUDRA GMP format.
19/12/2008	Variation to update licence, remove Applied Analysis Limited contract laboratory 4776 and add FDAS and Molecular Identification Services Unit contract laboratories. Remove site 3598 as a contract laboratory. Remove site 2755. Update licence to EUDRA GMP format and make requested amendments.
29/12/2008	Internal variation to amend licence.
12/01/2009	Internal variation to amend licence, removing the authorisation for section 1.1.2.4 solids/implants also removing site 89689.
27/09/2010	Variation to add Mr Mark Andrews as an additional QP.



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01/09/2011	Variation to (1) Site 3598: remove packaging of other solid dosage forms and tablets, remove dry heat and gamma irradiation, remove Miss Joanna Michelle Beaufoy as QP (2) Delete Molecular Identification Services Unit (Site 27841) and add Herd Mundy Richardson Ltd (Site 4655)
18/04/2012	Variation to remove Mr M Santillo as Quality Controller and replace with Mr M Andrews, retain Mr santillo as QP.
23/09/2013	Internal variation to replace Site ID 2755 with 383461
11/10/2013	Variation to remove Mr Phil Bendell as PM and QP and add Ms Janet Draper as PM, site 3598
17/01/2014	Variation to add Contract Laboratory JC Analytical.
01/04/2014	Variation to add Dr Peter Adams as a contract QP to site ID 3598.
07/05/2014	Variation to remove Production Manager Ms Jane Draper from site 3598 and add Mr David Hine as Production Manager to site 3598.
28/10/2014	Variation to add a new Quality Control Laboratory
19/12/2014	Variation to site 3598: add Mr A Bosley as QP.
11/05/2015	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
13/07/2015	Variation to add export to sites 11009752 and 90482
11/08/2015	Variation to delete Mr Mark Santillo (QP) from site 3598
28/08/2015	Internal variation to amend site contact for site 90482 from Mr P Blendell to Mark Andrews
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: 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 Dr Peter Adams as a QP. Site 3598: Remove Sally Andrews as SC. Add Mr Mark Christopher Colin Andrews as SC.
21/09/2016	Variation: Add Secondary Packaging (Sites 3598 & 11009752)
28/09/2016	Variation: Site 11009752 - replace Mark Andrews with Mr Alex Bosley as QC (but keep both as QP) - remove Mr Ashley Noyce (site contact) - 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



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28/11/2016	Variation: (Site 11009752) Add Manufacture site type and functions (small volume liquids)
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
20/08/2018	Variation (site 11009752): Add importation; Replace the Head of Production with Mrs Adrienne Kennedy
28/09/2018	Variation to add site 38651.
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 from site 11009752 -Add Alison Webber and Rebecca Smith as QC to site 11009752
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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MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

Manufacturer's/Importer's Licence

SECTION 3

ANNEX 1 - 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 Medicinal Products

AUTHORISED OPERATIONS

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



ANNEX 1 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS

- 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 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	Terminally Sterilised (processing operations for the following dosage forms)	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	Batch certification	Authorised



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1.2	Non-sterile 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 medicinal products	Manufacture
1.3.1	<i>Biological medicinal products</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 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
	1.4.1.4 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)	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



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1.4.3	Others	Not Authorised
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1.5	Packaging	Manufacture
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	Manufacture
	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 1 – SITE INFORMATION (continued)

Part 2 – IMPORTATION OF 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



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	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
	2.3.5 Products authorised under regulation 174 (supply in response to spread of pathogenic agents etc)	Not 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
20260179	Miss Gabrielle Kelsey	No	No	Yes	No
127165	Dr Julian C Smith	Yes	No	No	No
20177946	Miss Rebecca Smith	No	No	No	Yes
20260183	Mr Jamie Hoyle	No	No	Yes	No
1284910	Mr Ross Walker	Yes	No	No	Yes
376579	Mr Mark Christopher Colin Andrews	Yes	No	No	No
1282631	Mr Alex Bosley	Yes	No	No	No

Key to Roles:

QP – Qualified Person

TQP – Transitional Qualified Person

PM – Production Manager/Supervisor

QC – Person responsible for Quality Control



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ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
4655	HERD MUNDY RICHARDSON LIMITED	OAK HOUSE, BREDBURY PARK WAY, ASHTON ROAD, BREDBURY, STOCKPORT, SK6 2SN, UNITED KINGDOM
30429	HONEYMAN GROUP LIMITED	HARMIRE ENTERPRISE PARK, BARNARD CASTLE, DL12 8BN, UNITED KINGDOM
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