



Medicines & Healthcare products  
Regulatory Agency



**MHRA**

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United Kingdom

[gov.uk/mhra](https://gov.uk/mhra)

Sally Andrews  
TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST  
QUALITY CONTROL  
TORBAY HOSPITAL  
LAWES BRIDGE  
NEWTON ROAD  
TORQUAY  
TQ2 7AA  
UNITED KINGDOM



MS NUMBER: MS 13079

Version: 34

**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**

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

**Manufacturer's "Specials" Licence**

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**SECTION 1A**

**1. Licence Number**

MS Number: MS 13079

**2. Name of Licence Holder**

TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST

**3. Trading Style**

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

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

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

**5. Legally registered address of Licence Holder**

|                                                                          |
|--------------------------------------------------------------------------|
| TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4 7FG, UNITED KINGDOM |
|--------------------------------------------------------------------------|

**6. Scope of authorisation 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 these regulations.
2. It authorises the processes of manufacture and/or assembly and/or importation to which regulation 167 of The Human Medicines Regulations 2012 (SI 2012/1916) applies, 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 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 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.
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 accord 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 or assembly;
- b) ensuring a satisfactory turnover of stock of medicinal products;
- c) maintaining records of production, of analytical and other testing procedures;
- 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

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](http://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 signature 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 MHRA and to mark or destroy superseded pages as to render them invalid.



## MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

### Manufacturer's "Specials" Licence

#### SECTION 2

#### VARIATION HISTORY

This page will be amended if the licence is varied.

| Date       | Variation Detail                                                                                                                                                                                                                      |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01/01/1993 | Initial application                                                                                                                                                                                                                   |
| 03/04/1996 | Add a new site at Kemmings Close, Paignton.                                                                                                                                                                                           |
| 25/01/1999 | Renewal with changes: change of LH contact from Mr Costley to Mr Bendell; change of phone/fax; add Cm,Xm and Dv;delete Ca and As.(all at Kemmings Close site); change of SC from Mr Costley to Mr Bendell.                            |
| 24/09/2002 | Variation to add AT sites to licence.                                                                                                                                                                                                 |
| 15/11/2002 | Variation to add storage and handling site at Unit 7, Torbay Business Park, Paignton.                                                                                                                                                 |
| 04/12/2003 | Renewal with changes to change licence holder's address and add category Ca at site 8829.                                                                                                                                             |
| 11/05/2007 | Variation 1. Add Mr Mark Santillo as new QC. 2. Remove Dr Haines-Nutt as QC. 3. Add new site Applied Analysis Ltd.                                                                                                                    |
| 26/09/2008 | Change of company name from South Devon Healthcare NHS Trust to South Devon Healthcare NHS Foundation Trust.                                                                                                                          |
| 16/12/2008 | Variation to amend licence, remove contract laboratory Applied Analysis Limited, add FDAS and Molecular Identification Services contract laboratories. Add storage and handling site 90482. Remove site 2755.                         |
| 09/03/2010 | Variation to add additional Contract Laboratory; Quality Control West Midlands, Pharmacy , University Hospitals Birmingham NHS Foundation Trust, Kings Norton Business Centre, 32-34 Melchett Road, Kings Norton, Birmingham, B30 3HS |
| 09/09/2011 | Variation to remove sites 27841 & 1237049 (Molecular Identification Services Unit and University Hospital Birmingham NHS Foundation Trust) and add Site 4655 (Herd Mundy Richardson Ltd)                                              |
| 18/04/2012 | Variation to remove Mr M Santillo as Quality Controller and replace with Mr M Andrews, remove site 89689.                                                                                                                             |
| 11/10/2013 | Variation to remove Mr Phil Bendell and replace with Ms Janet Draper as PM, site 3598                                                                                                                                                 |
| 17/01/2014 | Variation to add Contract Laboratory JC Analytical.                                                                                                                                                                                   |



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|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16/04/2014 | Variation to delete Ms Janet Draper, Head of Production from site 3598 and to add Mr David Hine, Head of Production to site 3598.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 27/10/2014 | Variation to add a new Quality Control Laboratory testing site                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 19/12/2014 | Variation to change the address of the licence holder from South Devon Healthcare NHS Foundation Trust, Torbay PMU, Long Road, Paignton, TQ4 7TW to: □South Devon Healthcare NHS Foundation Trust, Torbay Pharmaceuticals, Wilkins Drive, Paignton, TQ4 7FG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 13/07/2015 | Variation to add export to site 3598, 11009752 and 90482                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 01/12/2015 | Variation:<br>Remove Site 90482 (SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST).<br>Add Trading style as Torbay Pharmaceuticals.<br>Change name of Site 3598 to Torbay and South Devon NHS Foundation Trust.<br>Change Address Line 1 from Pharmaceutical Manufacturing Unit to Torbay Pharmaceuticals.<br>Authorisation holder name corrected to Mr P S Bendell.<br>Update Authorisation holder address to Head Office, Hengrave House, Torbay Hospital, Torquay TQ2 7AA.<br>Site 11009752:<br>Remove Mr Ashley Noyce as SC.<br>Add Mr Mark Christopher Colin Andrews as SC and QC.<br>Add Mr David Hine as a PM.<br>Site 3598:<br>Remove Mr Mark Santillo as QP.<br>Update Mr Mark Christopher Colin Andrews as SC.<br>Add Contract Laboratory (Scottish Blood Transfusion Service). |
| 01/12/2015 | Internal Variation to remove QPs Mr Mark Christopher Colin Andrews and Mr M Santillo from site 3598                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 06/06/2016 | Internal Variation: 1. Delete site 90482. 2. Site 11009752 Add Mr David Hine as a PM. 3. Add Mr Mark Andrews as a QC. 4. Site 3598 change name to Scottish Blood Transfusion Service.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 21/09/2016 | Variation:<br>Add Secondary Packaging (Site 11009752)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 28/09/2016 | Variation:<br>Site 11009752<br>- replace Mark Andrews with Mr Alex Bosley (1282631) as QC<br>Site 3598<br>- replace Mark Andrews with Mr Alex Bosley (1282631) as QC<br>- add CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST (Site 431097) as a contract manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 28/11/2016 | Variation: (Site 11009752)<br>Add Manufacture site type and functions (small volume liquids)<br>Amend Communications address (Kemmings Close, TQ4 7TW)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |



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|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 06/02/2017 | Variation:<br>Correct site name for site 3598 TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST<br>Remove Contract Laboratory, Storage & Handling, Dry Heat, Gamma Irradiation and remove Ashley Noyce as SC (Site 11009752)<br>Add Manufacturing, Large volume liquids (Site 11009752)<br>Add Mr Mark Christopher Colin Andrews as SC (Site 11009752)<br>Remove Storage & Handling and QC testing (Site 3598)<br>Remove SOUTH DEVON HEALTHCARE NHS FOUNDATION TRUST (Site 90482)<br>Remove CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST (Site 431097) |
| 31/08/2017 | variation:<br>- delete site 3598 from the licence<br>- add Helvic Laboratories as a contract Lab                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 03/09/2018 | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 21/01/2020 | Variation<br>-Remove Alex Bosley from site 11009752<br>-Add Alison Webber and Rebecca Smith as QC's 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                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 23/03/2020 | Internal Variation to remove Batch Certification from site 11009752                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 20/04/2020 | Variation (site 11009752 ) to:<br>-Remove Mrs Adrienne Kennedy & Mr David Hine as PM's.<br>-Add Mr Gareth Price as QC.                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 24/04/2020 | Variation to add site 19259723                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 27/11/2020 | Variation (site 11009752) to replace Mr Gareth Price with Mr Ross Walker as QC.                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |



**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**

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

## Manufacturer's "Specials" Licence

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### SECTION 3

#### ANNEX 1 - SITE INFORMATION

##### SCOPE OF AUTHORISATION

###### NAME AND ADDRESS OF SITE:

|                          |                                                                             |
|--------------------------|-----------------------------------------------------------------------------|
| <b>SITE NAME:</b>        | TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST                                 |
| <b>ADDRESS:</b>          | TORBAY PHARMACEUTICALS, WILKINS DRIVE, PAIGNTON, TQ4<br>7FG, UNITED KINGDOM |
| <b>MHRA SITE NUMBER:</b> | 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 |



| <b>1.1.2</b> | <b><i>Terminally Sterilised (processing operations for the following dosage forms)</i></b> | <b>Manufacture</b> |
|--------------|--------------------------------------------------------------------------------------------|--------------------|
|              | 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     |



| 1.2   | Non-sterile products                                                                      | Manufacture    |
|-------|-------------------------------------------------------------------------------------------|----------------|
| 1.2.1 | <b><i>Non-Sterile Products (processing operations for the following dosage forms)</i></b> |                |
|       | 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 |
|       | 1.2.1.14 Transdermal patches                                                              | Not Authorised |
|       | 1.2.1.15 Other non-sterile medicinal products                                             | Not Authorised |



| <b>1.3</b>   | <b>Biological medicinal products</b>        | <b>Manufacture</b> |
|--------------|---------------------------------------------|--------------------|
| <b>1.3.1</b> | <b><i>Biological medicinal products</i></b> |                    |
|              | 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 Other biological medicinal products | Not Authorised     |



|              |                                                                                                                                                                                                                                                                                                                                                                       |                    |
|--------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| <b>1.4</b>   | <b><i>Other products or manufacturing activity</i></b><br>(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). | <b>Manufacture</b> |
| <b>1.4.1</b> | <b>Manufacture of:</b>                                                                                                                                                                                                                                                                                                                                                |                    |
|              | 1.4.1.1 Herbal products                                                                                                                                                                                                                                                                                                                                               | Not Authorised     |
|              | 1.4.1.2 Homoeopathic products                                                                                                                                                                                                                                                                                                                                         | Not Authorised     |
|              | 1.4.1.3 Biological active starting materials                                                                                                                                                                                                                                                                                                                          | Not Authorised     |
|              | 1.4.1.4 Other                                                                                                                                                                                                                                                                                                                                                         | Not Authorised     |
| <b>1.4.2</b> | <b>Sterilisation of active substances/excipients/finished products:</b>                                                                                                                                                                                                                                                                                               |                    |
|              | 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     |
| <b>1.4.3</b> | <b>Others</b>                                                                                                                                                                                                                                                                                                                                                         | Not Authorised     |



| <b>1.5</b>   | <b>Packaging</b>                              | <b>Manufacture</b> |
|--------------|-----------------------------------------------|--------------------|
| <b>1.5.1</b> | <b>Primary packing</b>                        |                    |
|              | 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              | Not Authorised     |
|              | 1.5.1.6 Liquids for internal use              | Not 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                          | Not Authorised     |
|              | 1.5.1.12 Suppositories                        | Not Authorised     |
|              | 1.5.1.13 Tablets                              | Not Authorised     |
|              | 1.5.1.14 Transdermal patches                  | Not Authorised     |
|              | 1.5.1.15 Other non-sterile medicinal products | Not Authorised     |
| <b>1.5.2</b> | <b>Secondary packing</b>                      | Authorised         |



| <b>1.6</b> | <b>Quality control testing</b>              | <b>Manufacture</b> |
|------------|---------------------------------------------|--------------------|
|            | <b>1.6.1 Microbiological: sterility</b>     | Authorised         |
|            | <b>1.6.2 Microbiological: non-sterility</b> | Authorised         |
|            | <b>1.6.3 Chemical/Physical</b>              | Authorised         |
|            | <b>1.6.4 Biological</b>                     | Not Authorised     |

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



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**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

| <b>2.1</b>   | <b>Imported medicinal products</b>                                           | <b>Import</b>  |
|--------------|------------------------------------------------------------------------------|----------------|
| <b>2.1.1</b> | Unlicensed medicinal products are imported from outside the EEA at this site | 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**

| <b><u>Person Number</u></b> | <b><u>Name</u></b>                | <b><u>Personnel Type</u></b> |                  |
|-----------------------------|-----------------------------------|------------------------------|------------------|
|                             |                                   | <b><u>PM</u></b>             | <b><u>QC</u></b> |
| 1284910                     | Mr Ross Walker                    | No                           | Yes              |
| 20177946                    | Miss Rebecca Smith                | No                           | Yes              |
| 376579                      | Mr Mark Christopher Colin Andrews | No                           | No               |
| 1471059                     | Dr Alison Webber                  | No                           | Yes              |
| 20260179                    | Miss Gabrielle Kelsey             | Yes                          | No               |
| 20260183                    | Mr Jamie Hoyle                    | Yes                          | No               |

**Key to Roles:**

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<br>RICHARDSON LIMITED             | OAK HOUSE, BREDBURY PARK WAY,<br>ASHTON ROAD, BREDBURY, STOCKPORT,<br>SK6 2SN, UNITED KINGDOM               |
| 30429             | HONEYMAN GROUP<br>LIMITED                    | HARMIRE ENTERPRISE PARK, BARNARD<br>CASTLE, DL12 8BN, UNITED KINGDOM                                        |
| 37653             | JC ANALYTICAL LIMITED                        | UNIT A, FLORENCE ROAD BUSINESS PARK,<br>KELLY BRAY, CALLINGTON, PL17 8EX,<br>UNITED KINGDOM                 |
| 38651             | READING SCIENTIFIC<br>SERVICES LIMITED       | READING SCIENCE CENTRE,<br>WHITEKNIGHTS CAMPUS, PEPPER LANE,<br>READING, RG6 6LA, UNITED KINGDOM            |
| 89536             | FOOD & DRUG<br>ANALYTICAL SERVICE<br>LIMITED | BIOCITY, PENNYFOOT STREET,<br>NOTTINGHAM, NG1 1GF, UNITED KINGDOM                                           |
| 2968688           | HELVIC LIMITED                               | UNIT E4, TRENTAM BUSINESS QUARTER,<br>BELLRINGER ROAD, TRENTAM, STOKE-<br>ON-TRENT, ST4 8GB, UNITED KINGDOM |
| 18816940          | READING SCIENTIFIC<br>SERVICES LIMITED       | 2-3 MILLARS BUSINESS CENTRE,<br>FISHPONDS CLOSE, WOKINGHAM, RG41<br>2TZ, UNITED KINGDOM                     |
| 19259723          | TEPNEL PHARMA<br>SERVICES LIMITED            | APPLETON PLACE, APPLETON PARKWAY,<br>LIVINGSTON, EH54 7EZ, UNITED KINGDOM                                   |