Medicines & Healthcare products Regulatory Agency

MHRA

MS NUMBER: MS 49464 Version: 3

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 1A

1. Licence Number

MS Number: MS 49464

2. Name of Licence Holder

ENTEROBIOTIX LIMITED

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 NUMBER:	SITE NAME:	ADDRESS:
18321324	ENTEROBIOTIX LIMITED	ABERDEEN BLOOD TRANSFUSION CENTRE, FORESTERHILL ROAD, ABERDEEN, AB25 2ZW, UNITED KINGDOM

5. Legally registered address of Licence Holder

ABERDEEN BLOOD TRANSFUSION CENTRE, FORESTERHILL ROAD, ABERDEEN, AB25 2ZW, 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

Emanuela Krasteva

SECTION 1A (continued)

9. Date 06/09/2018

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.

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 & Healthcare products Regulatory Agency

MHRA

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Manufacturer's "Specials" Licence

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
30/08/2018	Initial application
30/08/2018	Internal variation (site 18321324) Remove Microbiological (Sterility) QC testing; Add Animal Human Origin products to site type
06/09/2018	Internal variation to amend authorisation holder registered address

Medicines & Healthcare products Regulatory Agency

MHRA

MS NUMBER: MS 49464 MHRA Site No: 18321324 VERSION: 3

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 3

ANNEX 1 - SITE INFORMATION

SCOPE OF AUTHORISATION

NAME AND ADDRESS OF SITE:

SITE NAME:	ENTEROBIOTIX LIMITED
ADDRESS:	ABERDEEN BLOOD TRANSFUSION CENTRE, FORESTERHILL ROAD, ABERDEEN, AB25 2ZW, UNITED KINGDOM
MHRA SITE NUMBER:	18321324

TYPE OF PRODUCTS HANDLED

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to Part 1)	Authorised
Importation of Medicinal Products (according to Part 2)	Not 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

1.1.2	***Terminally Sterilised (processing operations for the following dosage forms)***	**Manufacture**
	1.1.2.1 Large volume liquids	Not Authorised
	1.1.2.2 Semi-solids	Not Authorised
	1.1.2.3 Small volume liquids	Not 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	***Non-Sterile Products (processing operations for the following dosage forms)***	
	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	Not 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 faecal microbiota	Authorised

1.3	**Biological medicinal products**	**Manufacture**
1.3.1	***Biological medicinal products***	
	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	Authorised
	1.3.1.7 Other biological medicinal products *faecal microbiota*	Authorised

1.4	***Other products or manufacturing activity*** (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 Biological active starting materials	Not Authorised
	1.4.1.4 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	Not 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

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

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

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

ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

Person Number	Name	Personnel Type	
		PM	QC
12803412	Mr Edwin Lindsay	No	Yes
4112837	Mr Nicolas Robinson	Yes	No

Key to Roles:

PM – Production Manager/Supervisor
QC – Person responsible for Quality Control

ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
41013	NCIMB LIMITED	FERGUSON BUILDING, CRAIBSTONE ESTATE, BUCKSBURN, ABERDEEN, AB21 9YA, UNITED KINGDOM

ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
18321324	ENTEROBIOTIX LIMITED	ABERDEEN BLOOD TRANSFUSION CENTRE, FORESTERHILL ROAD, ABERDEEN, AB25 2ZW, UNITED KINGDOM