MHRA
Regulating Medicines and Medical Devices

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Mr Paul Chenery
RUTLAND BIODYNAMICS LIMITED
TOWN PARK FARM
OAKHAM ROAD
BROOKE
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LE15 8DG
UNITED KINGDOM

Medicines and Healthcare
Products Regulatory Agency

MIA NUMBER: MIA 28255 Version: 7

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 28255

2. Name of Licence Holder

RUTLAND BIODYNAMICS 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:
123039	RUTLAND BIODYNAMICS LIMITED	TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM

5. Legally registered address of Licence Holder

TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM

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

Sean Kaiser

SECTION 1A (continued)

9. Date 04/04/2016

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.

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Manufacturer's/Importer's Licence

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
11/12/2006	Initial application.
11/12/2006	Internal variation to recreate licence in the new format.
23/09/2008	Variation to add additional activities., add Miss K Stokes as QP and QC., add Mr T Mayers as PM., add Mr B Lazonby as QP and to remove Mr A Tabram and Mr M Waldron as PM and QC respectively.
30/09/2008	Update licence to EUDRA GMP format
21/02/2013	Variation to remove Kate Stokes as Transitional Qualified Person and Quality controller. Replace Brian Lazonby as QP with Paul Anderson and add Michael Fornalcysk as QC
11/03/2016	Variation to site 123039 to remove pink antiseptic ointment, replace Tim Mayers with Paul Chenery as production manager, to replace Michael Formalczyk with Juan Escolano Molino as Quality controller, add sites 89536, 93666, 92250
04/04/2016	Internal Variation to site 123039 to remove Tim Mayers as Production Manager.

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SECTION 3

ANNEX 1 - SITE INFORMATION

SCOPE OF AUTHORISATION

NAME AND ADDRESS OF SITE:

SITE NAME:	RUTLAND BIODYNAMICS LIMITED
ADDRESS:	TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM
MHRA SITE NUMBER:	123039

TYPE OF PRODUCTS HANDLED

Human Medicinal Products

AUTHORISED OPERATIONS

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

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 Licensed
	1.1.1.2 Lyophilisates	Not Licensed
	1.1.1.3 Semi-solids	Not Licensed
	1.1.1.4 Small volume liquids	Not Licensed
	1.1.1.5 Solids and implants	Not Licensed
	1.1.1.6 Other aseptically prepared products	Not Licensed

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

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 Licensed
	1.2.1.2 Capsules, soft shell	Not Licensed
	1.2.1.3 Chewing gums	Not Licensed
	1.2.1.4 Impregnated matrices	Not Licensed
	1.2.1.5 Liquids for external use	Licensed
	1.2.1.6 Liquids for internal use	Licensed
	1.2.1.7 Medicinal gases	Not Licensed
	1.2.1.8 Other solid dosage forms	Not Licensed
	1.2.1.9 Pressurised preparations	Not Licensed
	1.2.1.10 Radionuclide generators	Not Licensed
	1.2.1.11 Semi-solids	Licensed
	1.2.1.12 Suppositories	Not Licensed
	1.2.1.13 Tablets	Not Licensed

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

1.3	Biological medicinal products	Manufacture
1.3.1	***Biological medicinal products***	
	1.3.1.1 Blood products	Not Licensed
	1.3.1.2 Immunological products	Not Licensed
	1.3.1.3 Cell therapy products	Not Licensed
	1.3.1.4 Gene therapy products	Not Licensed
	1.3.1.5 Biotechnology products	Not Licensed
	1.3.1.6 Human or animal extracted products	Not Licensed
	1.3.1.7 Tissue Engineered Products	Not Licensed
	1.3.1.8 Other biological medicinal products	Not Licensed
1.3.2	***Batch certification***	
	1.3.2.1 Blood products	Not Licensed
	1.3.2.2 Immunological products	Not Licensed
	1.3.2.3 Cell therapy products	Not Licensed
	1.3.2.4 Gene therapy products	Not Licensed
	1.3.2.5 Biotechnology products	Not Licensed

	1.3.2.6 Human or animal extracted products	Not Licensed
	1.3.2.7 Tissue Engineered Products	Not Licensed
	1.3.2.8 Other biological medicinal products	Not Licensed

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	Licensed
	1.4.1.2 Homoeopathic products	Not Licensed
	1.4.1.3 Other Manufacture API's	Licensed
1.4.2	**Sterilisation of active substances/excipients/finished products:**	
	1.4.2.1 Filtration	Not Licensed
	1.4.2.2 Dry heat	Not Licensed
	1.4.2.3 Moist heat	Not Licensed
	1.4.2.4 Chemical	Not Licensed
	1.4.2.5 Gamma irradiation	Not Licensed
	1.4.2.6 Electron beam	Not Licensed
1.4.3	**Others**	Not Licensed

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

	1.5.1.15 Other non-sterile medicinal products	Not Licensed
1.5.2	**Secondary packing**	Licensed

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

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

	2.2.3.4 Gene therapy products	Not Licensed
	2.2.3.5 Biotechnology products	Not Licensed
	2.2.3.6 Human or animal extracted products	Not Licensed
	2.2.3.7 Tissue Engineered Products	Not Licensed
	2.2.3.8 Other biological medicinal products	Not Licensed
2.3	**Other Importation Activities**	
	2.3.1 Site of Physical Importation	Not Licensed
	2.3.2 Importation of Intermediate which undergoes further processing	Not Licensed
	2.3.3 Other	Not Licensed

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

ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

Person Number	Name	Personnel Type			
		QP	TQP	PM	QC
120442	Mr Paul Anderson	Yes	No	No	No
630169	Mr Paul Chenery	No	Yes	Yes	No
13907257	Mr Juan Escolano Molina	No	No	No	Yes

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:
89536	FOOD & DRUG ANALYTICAL SERVICE LIMITED	BIOCITY, PENNYFOOT STREET, NOTTINGHAM, NG1 1GF, UNITED KINGDOM
92250	ALS FOOD AND PHARMACEUTICAL	2 BARTHOLOMEWS WALK, CAMBRIDGESHIRE BUSINESS PARK, ELY, CB7 4ZE, UNITED KINGDOM
93666	JC ANALYTICAL LIMITED	FLORENCE ROAD INDUSTRIAL ESTATE, KELLY BRAY, CALLINGTON, PL17 8EX, UNITED KINGDOM

ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
123039	RUTLAND BIODYNAMICS LIMITED	TOWN PARK FARM, OAKHAM ROAD, BROOKE, OAKHAM, LE15 8DG, UNITED KINGDOM