

Safeguarding public health

MHRA


COVANCE CLINICAL RESEARCH UNIT LIMITED
SPRINGFIELD HOUSE
HYDE STREET
LEEDS
WEST YORKSHIRE
LS2 9LH
UNITED KINGDOM



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Medicines Act 1968

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1A

1. Authorisation Number

MIA(IMP) Number: MIA(IMP) 13101

2. Name of Authorisation Holder

COVANCE CLINICAL RESEARCH UNIT LIMITED

3. 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:
21095	COVANCE CLINICAL RESEARCH UNIT LIMITED	SPRINGFIELD HOUSE, HYDE STREET, LEEDS, WEST YORKSHIRE, LS2 9LH, UNITED KINGDOM

4. Legally registered address of Authorisation Holder

SPRINGFIELD HOUSE, HYDE STREET, LEEDS, WEST YORKSHIRE, LS2 9LH, UNITED KINGDOM

5. Scope of authorisation and dosage forms

See Annex 2

6. Legal basis of authorisation

See Section 1B of authorisation.

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



8. Date 31/03/2007





SECTION 1A (continued)

9. Annexes attached

Annex 2

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1B

1. This authorisation is granted in accordance with the provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] which implement Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001.
2. It permits the authorisation holder named on page 3 of Section 1 of the authorisation to manufacture, assemble and/or import investigational medicinal products for human use in accordance with Regulation 41 of the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended [S.I. 2004/1031] (as detailed in section 3 of this authorisation) and is subject to the provisions identified on page 2 of Section 1 of this authorisation.
3. In this document a Manufacturers Authorisation for Investigational Medicinal Products may be referred to as MIA(IMP) and the Medicines and Healthcare products Regulatory Agency (acting on behalf of the Licensing Authority as defined in Section 6 of the Medicines Act 1968 as amended) may be referred to as MHRA.
4. The authorisation holder must inform the MHRA, in advance, of any change to the details submitted by him and/or included in this authorisation. All changes must be approved by the MHRA to have effect. If the business should change hands, the company or person taking over the business will have to obtain a new authorisation before commencing the manufacture, assembly or importation of investigational medicinal products.

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



SECTION 1B (continued)

5. Authorisation Structure

This authorisation is divided into three sections.

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

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



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
05/04/2004	Initial application
03/01/2006	Remove [REDACTED] as Qualified Person Production Manager. Remove [REDACTED] as as Production Manager. [REDACTED] to be interim Production Manager
27/02/2006	Internal variation to correct discrepancies
28/02/2006	Internal variation to correct discrepancies also remove [REDACTED] as QP and QC Manager Neena - This needs to bypass the Inspectors.
30/07/2006	Add [REDACTED] as QP and QC
21/09/2006	Internal variation to amend licence and update to new format.
22/09/2006	Internal Variation to add contract Lab
31/03/2007	Amendments to licence addition of categories, also change to personnel, remove [REDACTED] as Production Manager, remove [REDACTED] as QP, Addition of [REDACTED] as Production. Addition of contract site (Leeds Teaching Hospitals)



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MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under the Medicines Act 1968

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	COVANCE CLINICAL RESEARCH UNIT LIMITED
ADDRESS:	SPRINGFIELD HOUSE, HYDE STREET, LEEDS, WEST YORKSHIRE, LS2 9LH, UNITED KINGDOM
MHRA SITE NUMBER:	21095

Type of products handled

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

Authorised operations

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



ANNEX 2 – SITE INFORMATION (continued)**Part 1 – MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS**

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

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



1.1.2	<i> terminally Sterilised</i>	Manufacture
	1.1.2.1 Large volume liquids	Authorised
	1.1.2.2 Semi-solids	Authorised
	1.1.2.3 Small volume liquids	Authorised
	1.1.2.4 Solids and implants	Not Authorised
	1.1.2.5 Other terminally sterilised prepared products	Not Authorised
1.1.3	<i>Batch certification only</i>	Authorised



1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	Non-sterile products (list of dosage forms)	
	1.2.1.1 Capsules, hard shell	Authorised
	1.2.1.2 Capsules, soft shell	Authorised
	1.2.1.3 Chewing gums	Authorised
	1.2.1.4 Impregnated matrices	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	Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Authorised
	1.2.1.12 Suppositories	Authorised
	1.2.1.13 Tablets	Authorised

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



1.3	Biological investigational medicinal products	Manufacture
1.3.1	<i>Biological medicinal products (list of product types)</i>	
	1.3.1.1 Blood products	Not Authorised
	1.3.1.2 Immunological products	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	Authorised
	1.3.1.6 Human or animal extracted products	Authorised
	1.3.1.7 Other biological medicinal products	Not Authorised
1.3.2	<i>Batch certification only (list of product types)</i>	
	1.3.2.1 Blood products	Not Authorised
	1.3.2.2 Immunological products	Authorised
	1.3.2.3 Cell therapy products	Not Authorised
	1.3.2.4 Gene therapy products	Not Authorised
	1.3.2.5 Biotechnology products	Authorised
	1.3.2.6 Human or animal extracted products	Authorised
	1.3.2.7 Other biological medicinal products	Not Authorised



1.4	<i>Other investigational medicinal products or manufacturing activity</i> (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	Manufacture
1.4.1	Manufacture of:	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 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 only	Packaging
1.5.1	Primary packing	
	1.5.1.1 Capsules, hard shell	Authorised
	1.5.1.2 Capsules, soft shell	Authorised
	1.5.1.3 Chewing gums	Authorised
	1.5.1.4 Impregnated matrices	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	Authorised
	1.5.1.9 Pressurised preparations	Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Authorised
	1.5.1.12 Suppositories	Authorised
	1.5.1.13 Tablets	Authorised
	1.5.1.14 Transdermal patches	Authorised
	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	Secondary packing	Authorised





1.6	Quality control testing	
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Not 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 2 – SITE INFORMATION (continued)****Part 2 – IMPORTATION OF INVESTIGATIONAL MEDICINAL PRODUCTS**

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

2.1	Quality control testing	Import
	2.1.1 Microbiological: sterility	Not Authorised
	2.1.2 Microbiological: non-sterility	Not Authorised
	2.1.3 Chemical/Physical	Not 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	Authorised
	2.2.3.3 Cell therapy products	Not Authorised





	2.2.3.4 Gene therapy products	Not Authorised
	2.2.3.5 Biotechnology products	Authorised
	2.2.3.6 Human or animal extracted products	Authorised
	2.2.3.7 Other biological medicinal products	Not Authorised
2.2.4	<i>Other importation activities</i> (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)	
	2.2.4.1 Radiopharmaceuticals/Radionuclide generators	Authorised
	2.2.4.2 Medicinal gases	Not Authorised
	2.2.4.3 Herbal products	Not Authorised
	2.2.4.4 Homeopathic products	Not Authorised
	2.2.4.5 Biological active starting materials	Not Authorised
	2.2.4.6 Other	Not Authorised

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
		Yes	No	No	Yes
		Yes	No	No	No
		Yes	No	No	No
		Yes	No	No	Yes
		Yes	No	No	No
		No	No	Yes	No

Key to Roles:

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





ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
27679	COVANCE LABORATORIES EUROPE (HARROGATE)	OTLEY ROAD, HARROGATE, NORTH YORKSHIRE, HG3 1PY, UNITED KINGDOM
343141	LEEDS TEACHING HOSPITALS PHARMACY/QUALITY CONTROL LABORATORY	MOOR HOUSE, 125 MOOR ROAD, HUNSLET, LEEDS, WEST YORKSHIRE, LS10 2JQ, UNITED KINGDOM



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ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
21095	COVANCE CLINICAL RESEARCH UNIT LIMITED	SPRINGFIELD HOUSE, HYDE STREET, LEEDS, WEST YORKSHIRE, LS2 9LH, UNITED KINGDOM

