



MIA(IMP) MIA(IMP) 32879
NUMBER:

Version: 8

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 1A

1. Authorisation Number

MIA(IMP) Number: MIA(IMP) 32879

2. Name of Authorisation Holder

VERTICAL PHARMA RESOURCES 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:
93706	VERTICAL PHARMA RESOURCES LIMITED	41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM

5. Legally registered address of Authorisation Holder

41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM

6. Scope of authorisation and dosage forms

See Annex 2

7. Legal basis of authorisation

See Section 1B of authorisation.





MIA(IMP) MIA(IMP) 32879
NUMBER:

Version: 8

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

Olumuyiwa Abimbola

SECTION 1A (continued)

9. Date 13/01/2020

10. 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

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

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 1 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 Regulation 6 of The Human Medicines Regulations 2012 (SI 2012/1916) 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.
-

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

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

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
18/08/2015	MIA(IMP) Initial:VERTICAL PHARMA RESOURCES LIMITED
21/09/2015	Variation to add additional Qualified Person Mrs Angela Thomas and re-instate 1.5.1.5.
14/03/2016	Variation: Add new contract laboratory site id10689377.
04/11/2016	Variation to update site types and site activities on site 93706
06/08/2018	Variation: add Dr Andrew Duffield as QC; add Andrew Froome as PM
09/01/2019	Variation to: ☐ Remove Mr Paul Went as QC, remove Mr Amar Shah as PM and remove Mrs Angela Christina Thomas as QP. ☐ Addition of Amanda Clare Peter as QP.
13/06/2019	Variation: - change site address of ARC PHARMA (UK) LIMITED (replace site 10689377 with site 18603487) - replace Andrew Froome with Krunal Prajapati (6211500) as PM on site 93706
13/01/2020	Internal variation.





MIA(IMP) MIA(IMP)
NUMBER: 32879

MHRA Site No: 93706

VERSION: 8

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

Manufacturer's Authorisation - Investigational Medicinal Products

SECTION 3

ANNEX 2 - SITE INFORMATION

SCOPE OF AUTHORISATION

Name and address of site:

SITE NAME:	VERTICAL PHARMA RESOURCES LIMITED
ADDRESS:	41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM
MHRA SITE NUMBER:	93706

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





MIA(IMP) MIA(IMP)
NUMBER: 32879

MHRA Site No: 93706

VERSION: 8

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 (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





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

1.1.2	<i>Terminally Sterilised (processing operations for the following dosage forms)</i>	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
1.1.3	<i>Batch certification</i>	Authorised





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	Non-Sterile Products (processing operations for the following dosage forms)	
	1.2.1.1 Capsules, hard shell	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	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	Authorised
	1.2.1.13 Tablets	Authorised





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products	Not Authorised
1.2.2	<i>Batch certification</i>	Authorised





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

1.3	Biological investigational medicinal products	Manufacture
1.3.1	Biological medicinal products (list of product types)	
	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	Batch certification	
	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





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

	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





MIA(IMP) MIA(IMP)
NUMBER: 32879

MHRA Site No: 93706

VERSION: 8

1.4	Other investigational medicinal 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	Authorised
	1.4.1.2 Homoeopathic products	Authorised
	1.4.1.3 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





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

1.5	Packaging	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	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	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	Authorised
	1.5.1.13 Tablets	Authorised





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

	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





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

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	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	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





MIA(IMP)
NUMBER:

MIA(IMP)
32879

MHRA Site No: 93706

VERSION: 8

	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	Authorised
	2.3.2 Importation of Intermediate which undergoes further processing	Authorised
	2.3.3 Biological Active Substances	Not Authorised
	2.3.4 Other	Not Authorised

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





MIA(IMP) MIA(IMP)
NUMBER: 32879

MHRA Site No: 93706

VERSION: 8

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>
145868	Dr Andrew Duffield	No	No	No	Yes
1239176	Mrs Angela Christina Thomas	Yes	No	No	No
625577	Ms Amanda Clare Peter	No	Yes	No	No
6211500	Mr Krunal Prajapati	No	No	Yes	No
128939	Mr David Keith Davies	Yes	No	No	No
2595191	Mr Ashokkumar Dahyabhai Lallubhai Patel	No	No	No	No

Key to Roles:

QP – Qualified Person

TQP – Transitional Qualified Person

PM – Production Manager/Supervisor

QC – Person responsible for Quality Control





MIA(IMP)
NUMBER:

MIA(IMP) 32879

VERSION: 8

ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
18603487	ARC PHARMA (UK) LIMITED	UNIT 3, CURO PARK, FROGMORE, ST. ALBANS, AL2 2DD, UNITED KINGDOM





MIA(IMP)
NUMBER:

MIA(IMP) 32879

VERSION: 8

ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
93706	VERTICAL PHARMA RESOURCES LIMITED	41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM





Medicines & Healthcare products
Regulatory Agency

Mr Ashokkumar Dahyabhai Lallubhai Patel
VERTICAL PHARMA RESOURCES LIMITED
41 CENTRAL AVENUE
WEST MOLESEY
KT8 2QZ
UNITED KINGDOM



MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra