



Certificate No: UK WDA(H) 32879 Insp GMP/GDP/IMP 32879/93706-0021

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Article 111 of Directive 2001/83/EC as amended.

The competent Authority of the United Kingdom confirms the following:

The Wholesale Distributor: VERTICAL PHARMA RESOURCES LIMITED

Site Address in the United Kingdom:

41 CENTRAL AVENUE
WEST MOLESEY
KT8 2QZ
UNITED KINGDOM

Has been inspected under the national inspection programme in connection with the authorisation required in accordance with Article 77 (1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 02/04/2019, it is considered that it complies with the principles of good distribution practice requirements referred to in Article 84 of Directive 2001/83/EC as amended.

This certificate reflects the status of the inspected site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is only valid when presented with all pages.

The authenticity of this certificate may be verified in the EUDRAGMDP database.

The authorisation of this wholesale distributor may be verified with the issuing authority.





Medicines & Healthcare products
Regulatory Agency



Certificate No: UK WDA(H) 32879 Insp GMP/GDP/IMP 32879/93706-0021

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Norman Gray
GDP Inspector
Norman.Gray@mhra.gov.uk

Date: 08/05/2019



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations
2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

1. This authorisation is granted in accordance with regulation 18 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of those Regulations and the Medicines Act 1971.
2. This Wholesale Distribution Authorisation authorises distribution by way of wholesale dealing of medicinal products for human use by the authorisation holder named and storage of such products only on the premises located in the United Kingdom as specified.
3. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the medicinal products. If any change of premises is proposed prior approval must be sought from the Licensing Authority. Any proposals to make structural alterations to the premises must also be notified to the Licensing Authority.
4. The authorisation is not transferable to another legal entity.
5. The authorisation holder must not sell or supply a medicinal product, or offer it for sale or supply, unless:
 - there is a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product
 - the sale or supply, or offer for sale or supply of the product is in accordance with the authorisation
 - the sale or supply of the medicinal is pursuant to an exemption from the requirements to hold such an authorisation (a special medicinal product), under the provisions of The Human Medicines Regulations 2012 (SI 2012/1916).
6. The authorisation holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of a special medicinal product, stating the name of the medicinal product, any trademark or name of the manufacturer and their address, each active constituent, the quantity to be imported in accordance with the provision of The Human Medicines Regulations 2012 (SI 2012/1916). The authorisation holder must be able to demonstrate compliance with the European Commission 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products' and future updates, in accordance with, The Unlicensed Medicines Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680]
7. If the intention is to import licensed medicinal products from outside the EEA an application for a manufacturer's licence that authorises import must be made and a licence granted for that purpose before commencing with this activity. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.



8. If the intention is to import a special medicinal product from outside the EEA into the UK, an application for a manufacturer's "Specials" licence that authorises import must also be made and a licence granted for that purpose before commencing with this activity. Such a licence requires only that a site contact be named, no Qualified Person is required.
9. If the intention is to carry out any manufacture and/or assembly processes (e.g. packing, filling or labelling) of medicinal products, an application for a manufacturer's licence must be made and a licence granted for that purpose before commencing with this activity.
10. This Wholesale Distribution Authorisation may be suspended if any fees are not paid in full as they fall due.
11. 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).
12. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.
13. Authorisation Structure

This Wholesale Distribution Authorisation is divided into five annexes.

- (a) Annex 1: Scope of wholesale distribution authorisation
- (b) Annex 2: (Optional) Address(es) of contract wholesale distribution sites and their authorisation number
- (c) Annex 3: Name(s) of responsible person(s.)
- (d) Annex 4: (Optional) Date of Inspection on which authorisation was granted
- (e) Annex 5: Additional provisions based on national requirements

Attention is drawn to the structure of this authorisation 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.



14. Authorisation Holder

(a) Authorisation Holder Number: WDA(H) 32879 has been granted to –

AUTHORISATION HOLDER:	VERTICAL PHARMA RESOURCES LIMITED
TRADING AS:	INTEGRATED PHARMACEUTICAL SERVICES (IPS)
ADDRESS:	41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM
CONTACT NAME:	Mr Ashokkumar Dahyabhai Lallubhai Patel

- (b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing within the EEA medicinal products of the description or general classification specified, to be stored at the named premises on this authorisation.
- (c) This authorisation will continue to remain in force from the date of issue by the Licensing Authority unless cancelled, suspended, revoked or varied as to the period of its validity or relinquished by the authorisation holder.
- (d) Date granted - 08/01/2019
- (e) Authorised by -

Name: Asif Janjua

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 08/01/2019



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
 On behalf of the Licensing Authority under The Human Medicines Regulations
 2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

VARIATION HISTORY

Date	Variation Detail
01/01/1993	INITIAL APPLICATION
26/09/1995	Addition of RP
15/04/1997	Renewal: Add Wc code to categories of products.
24/11/2000	Variation to add (Wu).
20/09/2002	Renewal with changes to revise address details, delete Sc and add Wx.
12/12/2003	Variation to add site 11761.
01/02/2008	Variation to change ownership from Herisse Ltd to Vertical Pharma Resources Limited.
30/09/2010	Internal Variation to amend LH contact, SC & RP details to Mr ADL Patel.
08/11/2010	Variation to add text and authorisation for Other Sterile Products and Other Non-sterile products site 93706.
04/02/2011	Variation to import on one occasion 35,000 x 3 x 1ml Prontogest injections (AMSA Srl) from Italy to meet public health needs, as agreed with DH, whilst the equivalent UK licensed product is unavailable.
15/02/2011	Variation to add authorisation for Biological Products site 93706
21/02/2012	Variation to remove Responsible Person Mr G Patel, from site 93706.
14/03/2012	Internal variation to authorise cold chain products, site 93706.
15/10/2013	FMD update WL/WDL converted to WDA(H)
08/01/2019	Variation to add Section 1.3 and add export as an authorised wholesale distribution operation. Also, to add Amanda Peter as an RP.





WDA(H) Number: WDA(H) 32879

MHRA Site No: 93706

Version: 2

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations
2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

Annex 1 – Scope of Wholesale Distribution Authorisation

The premises –

Site Name:	VERTICAL PHARMA RESOURCES LIMITED
Address:	41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM
MHRA Site Number:	93706

is named on Authorisation Holder number: WDA(H) 32879 and authorised to perform the following:

1. Those operations as specified
2. Those descriptions of products or classes of product as specified
3. The personnel named to carry out the roles as specified

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





Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

- 1.1 With a Marketing Authorisation in EEA member state(s)
- 1.2 Without a Marketing Authorisation in the EEA and intended for EEA market
- 1.3 Without a Marketing Authorisation in the EEA and not intended for EEA market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
 - 2.2 Holding
 - 2.3 Supply
 - 2.4 Export
 - 2.5 Other Activities
- Administration & Procurement

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art 83 of 2001/83/EC

- 3.1.1 Narcotic or psychotropic products
- 3.1.2 Medicinal products derived from blood
- 3.1.3 Immunological medicinal products

- 3.3 Cold chain products (requiring low temperature handling)





WDA(H) Number: WDA(H) 32879

MHRA Site No: 93706

Version: 2

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

Wholesale Distribution Authorisation (Human)

Annex 5 – Additional Provisions Based on National Requirements

Site Name:	VERTICAL PHARMA RESOURCES LIMITED
Address:	41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, UNITED KINGDOM
MHRA Site Number:	93706

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy
- 4.5 Traditional Herbal Medicinal products





MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under The Human Medicines Regulations
2012 (SI 2012/1916)

Wholesale Distribution Authorisation (Human)

Annex 3 – Name(s) of designated Responsible Person(s)

Personnel

<u>Responsible Person</u>			
<u>Person Number</u>	<u>Name</u>	<u>Site</u>	<u>Role</u>
2595191	Mr Ashokkumar Dahyabhai Lallubhai Patel	93706	Responsible Person
625577	Ms Amanda Clare Peter	93706	Responsible Person





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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 32879

2. Name of Licence Holder

VERTICAL PHARMA RESOURCES LIMITED

3. Trading Style

INTEGRATED PHARMACEUTICAL SERVICES (IPS)

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 Licence Holder

41 CENTRAL AVENUE, WEST MOLESEY, KT8 2QZ, 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

Olumuyiwa Abimbola





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SECTION 1A (continued)

9. Date 13/01/2020

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)





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 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 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
12/12/2003	New application
23/01/2008	Variation to add Mr G Patel, Mr S Odoom and Mr R Kurella as PM's., add Mr A Patel, Mrs T Cordozo and Mr S Kurella as QC's.
05/02/2008	Application to change ownership from Herisse Ltd to Vertical Pharma Resources Ltd.
25/01/2010	Internal variation to amend licence details.
26/01/2010	Internal variation to remove authorisation for Transdermal Patches from site 93706.
22/03/2010	Internal variation to correct error.
09/07/2010	Internal variation to correct error.
22/09/2010	Variation to change the communications address to; 41 Central Avenue, West Molesey, Surrey, KT8 2QZ
14/03/2012	Variation to remove Mr G Patel as Production Manager, add Mr K Prajapati as Production Manager and Quality Controller site 93706.
30/05/2012	Variation to amend site activities.
02/07/2012	Variation to site activities.
18/07/2012	Internal variation to clarify Primary Packing operations.
11/09/2012	Variation to add Contract Laboratory site 1992550: Select Pharma Laboratories Limited.
04/03/2013	INTERNAL VARIATION
10/06/2014	Variation to (1) remove Mr Krunal Prajapati as QC, remove Mr Rama Subbarao Kurella as PM and add Mrs B Patel and Mr A Shah as QC (2) Delete Zeta Analytical Ltd
29/09/2014	Variation to add two contract laboratory testing sites - Butterworth Laboratories Limited and Trinity Scientific Limited
03/10/2014	Internal variation to authorise chemical/physical testing for the Vertical Pharma site 93706.





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14/03/2016	Variation: Add new contract laboratory site id 10689377.
29/06/2018	Variation (site 93706): - replace Mrs Bela Patel with Mr Sujitkumar Singh as QC - replace Mr Krunal Prajapati with Mr Andrew Froome as PM
01/03/2019	Variation - add JC Analytical Limited (site 37653) as contract Lab - remove Trinity Scientific (site 6673013) from the license - update site functions to add hard capsule shells, Tablets, Liquids for internal use, Liquids for external use, semi-solids, suppositories, Chewing gums and transdermal patches for primary packaging on site 93706
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 to update LHC.





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

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





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





1.2	Non-sterile products	Manufacture
1.2.1	Non-Sterile Products (processing operations for the following dosage forms)	
	1.2.1.1 Capsules, hard shell	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
	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products Manufacture of "Specials" extemporaneous preparations (excluding Steriles) in all forms (including powders), strength and quality, primary packaging.	Authorised





1.3	Biological medicinal products	Manufacture
1.3.1	<i>Biological medicinal products</i>	
	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





1.4	<i>Other 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	Manufacture
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	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	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	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	Manufacture
	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:





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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

2.1	Imported medicinal products	Import
2.1.1	Unlicensed medicinal products are imported from outside the EEA at this site	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

<u>Person Number</u>	<u>Name</u>	<u>Personnel Type</u>	
		<u>PM</u>	<u>QC</u>
19438158	Mr Sujitkumar Singh	No	Yes
2595191	Mr Ashokkumar Dahyabhai Lallubhai Patel	No	No
6211500	Mr Krunal Prajapati	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:
5712	BUTTERWORTH LABORATORIES LIMITED	54-56 WALDEGRAVE ROAD, TEDDINGTON, TW11 8NY, UNITED KINGDOM
37653	JC ANALYTICAL LIMITED	UNIT A, FLORENCE ROAD BUSINESS PARK, KELLY BRAY, CALLINGTON, PL17 8EX, UNITED KINGDOM
1061254	MCS LABORATORIES LIMITED	UNITS 8 & 9, ROCKMILL BUSINESS PARK, THE DALE, STONEY MIDDLETON, HOPE VALLEY, S32 4TF, UNITED KINGDOM
1992550	SOURCE BIOSCIENCE LIMITED	55 STIRLING ENTERPRISE PARK, STIRLING, FK7 7RP, UNITED KINGDOM
18603487	ARC PHARMA (UK) LIMITED	UNIT 3, CURO PARK, FROGMORE, ST. ALBANS, AL2 2DD, UNITED KINGDOM





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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



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E14 4PU
United Kingdom

gov.uk/mhra



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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.





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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.





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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





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





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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





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1.2	Non-sterile investigational medicinal products	Manufacture
1.2.1	<i>Non-Sterile Products (processing operations for the following dosage forms)</i>	
	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





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	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





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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





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	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





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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	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





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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





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	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





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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





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	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:





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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





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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





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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



Certificate No: UK MIA(IMP) 32879 Insp GMP/GDP/IMP 32879/93706-0021

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	VERTICAL PHARMA RESOURCES LIMITED
Site address	41 CENTRAL AVENUE WEST MOLESEY KT8 2QZ UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA(IMP) 32879 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 02/04/2019, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear please contact the issuing authority.





Certificate No: UK MIA(IMP) 32879 Insp GMP/GDP/IMP 32879/93706-0021

Part 2

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

1. MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.3 Batch Certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

- 1.2.1.1 Capsules, hard shell
- 1.2.1.5 Liquids for external use
- 1.2.1.6 Liquids for internal use
- 1.2.1.8 Other solid dosage forms
- 1.2.1.11 Semi-solids
- 1.2.1.12 Suppositories
- 1.2.1.13 Tablets

1.2.2 Batch Certification

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

1.4.1 Manufacture of

- 1.4.1.1 Herbal products
- 1.4.1.2 Homeopathic products

1.5 Packaging

1.5.1 Primary packaging

- 1.5.1.1 Capsules, hard shell
- 1.5.1.2 Capsules, soft shell
- 1.5.1.5 Liquids for external use
- 1.5.1.6 Liquids for internal use
- 1.5.1.8 Other solid dosage forms
- 1.5.1.11 Semi-solids
- 1.5.1.12 Suppositories
- 1.5.1.13 Tablets

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products





2.1.3 Chemical/physical

2.2 Batch certification of imported medicinal products

2.2.1 Sterile Products

2.2.1.1 Aseptically prepared products

2.2.1.2 Terminally sterilised products

2.2.2 Non-sterile products

2.3 Other importation activities

2.3.1 Site of Physical Importation

2.3.2 Importation of Intermediate which undergoes further processing





Certificate No: UK MIA(IMP) 32879 Insp GMP/GDP/IMP 32879/93706-0021

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

Not Authorised

3.6 Quality Control Testing

Not Authorised

4 Other Activities

Not Authorised





Certificate No: UK MIA(IMP) 32879 Insp GMP/GDP/IMP 32879/93706-0021

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

N/A

5. Medicinal Product(s)/IMP(s)

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 08/05/2019





Home Office

UNITED KINGDOM CONTROLLED DRUG LICENCE

MISUSE OF DRUGS ACT 1971

The Misuse of Drugs Regulations 2001 (Regulations 5)

UNITED KINGDOM COMPETENT AUTHORITY: HOME OFFICE DRUGS & FIREARMS LICENSING (DFLU) DRUG LICENSING- DOMESTIC LICENSING PO BOX 2163 CROYDON CR90 9TA	LICENCE HOLDER REF NO.	1636
	LICENCE REF NO	638976
	ISSUE DATE	19 February 2020
	EXPIRY DATE	18 February 2021

Licensee- Vertical Pharma Resources Ltd T/A IPS Pharma 41 Central Avenue West Molesey Surrey KT8 2QZ	Licensed Premises: 41 Central Avenue West Molesey, Surrey KT8 2QZ
--	--

Is hereby granted a licence by the Secretary of State, in pursuance of the Misuse of Drugs Act 1971 (hereinafter called "the 1971 Act), in respect of drugs in the following Schedule(s) to the Misuse of Drugs Regulations 2001 SI 2001/3998 to:

Schedule 1 possess
Schedule 1 supply
Schedule 1 produce
Schedule 2 possess
Schedule 2 supply
Schedule 2 produce
Schedule 3 possess
Schedule 3 supply
Schedule 3 produce
Schedule 4 part 1 possess
Schedule 4 part 1 supply
Schedule 4 part 1 produce
Schedule 4 part 2 possess
Schedule 4 part 2 supply
Schedule 4 part 2 produce
Schedule 5 supply
Schedule 5 produce

The licence is valid in respect of the above drugs, including any stereoisometric forms, and any salts thereof, and any preparation or other product containing any proportion of the drug(s) or its/ their salts (hereinafter called "the drug(s)"), subject to the following conditions:

NOTES & SPECIAL CONDITIONS (made in accordance with the provisions of Section 10 of the Misuse of Drugs Act 1971)

Cannabis-based products for medicinal use in humans ("CBPM")

Substances that meet the definition of a CBPM in Regulation 2 of the Misuse of Drugs Regulations 2001 ('2001 Regulations') must be handled in accordance with the special measures of control for the use in the 2001 Regulations. Such orders and supply for the purpose of administration must be for:

- use in accordance with the prescription or direction of a specialist medical practitioner;
- an investigational medicinal product for use in a clinical trial in humans;
- Or, a medicinal product with a marketing authorisation.

The licensee must hold all relevant valid MHRA licence(s). Where the CBPM is to be imported as an unlicensed medicine for human use or 'special', 25 individual doses or a quantity that must not exceed that required for 25 courses of no more than 3 months can be held in response to a prescription for an individual patient. Copies of MHRA approved 'notifications' must be supplied with the corresponding application for Home Office import licence(s).

The Aurora 8/8 cannabis flower (schedule 1 substance) is to be used only for filling cartridges with 250mg & 500mg of the ground cannabis flower for research purposes being undertaken at Strathclyde university to test on an artificial lung to determine the dosage level.

Stocks of the 250mg & 500mg of the ground cannabis flower cartridges for the supply to the clinical trial CTA document that will be associated with your Controlled drugs application reference 2485521, no bulk stocks shall be held, they must be proportionate to that required by the clinical trial

Security

Stocks of drugs shall, at all times, be in the charge of the licensee or responsible person appointed by him and will be kept securely.

All drugs subject to the 'safe storage' provisions specified in the Misuse of Drugs (Safe Custody) Regulations 1973 (those listed in Schedules 1 and 2 & certain Schedule 3 drugs) shall be securely stored in accordance with those provisions.

Record Keeping

The licensee shall keep records: in accordance with the record keeping requirements set out in the Misuse of Drugs Regulations 2001, unless the provisions set out in regulation 19(3) apply. Those records, which may be in (bound) hard copy or electronic form, must be retained at the premises to which they relate, for a period of at least two years from the date the last entry is made. Where specified by the Regulations, 'registers' must be maintained in accordance with those Regulations. You may be required to produce in paper form pages from your computerised record.

The licence and any stocks of drugs shall be produced for inspection when required by any person duly authorised under section 23 of the 1971 Act.

In the event of the licensee ceasing to require a licence or licence(s) above at the licensed premises, or if the authority of the licence is revoked by the Secretary of State, the licensee shall return the licence immediately to the address below. The licensee must provide full details in respect of the destruction of any residual stocks of controlled drugs.

Authorised Witness

In accordance with the provisions of Regulation 27(1) of the Misuse of Drugs Regulations 2001:

Ashokkumar Dahyabhai Lallubhai Patel and Amanda Peter (hereinafter called "the authorised person") is hereby authorised to supervise the destruction of drugs in the above licensed schedules held at the licensee's premises. In accordance with regulation 27(3), any record that is kept in respect of the obtaining or supplying those drugs that are destroyed under the supervision of the authorised person shall include particulars of the dates of any such destruction, the quantities of the drug destroyed and shall be signed by the authorised person in whose presence the drug must be destroyed.

Thefts and Losses

The licensee must take reasonable precautions to safeguard theft or loss of any drugs in their possession. Thefts or losses should be notified immediately to the Police and the Home Office in writing.

Furnishing of information

The licensee must furnish the Secretary of State such information in relation to this licence as may be required, in accordance with the requirements set out in Regulation 26(1) to the Misuse of Drugs Regulations 2001.

In addition to the record keeping requirements detailed above, the licensee must provide the following information to the Head of Drug Licensing at the address below and where required, an 'Annual Statistical Return' **by the last day in January each year at the latest of:-**

- The amount of the drug in his possession or coming into his possession
- The amount of the drug supplied; and
- The amount of the drug used

THIS LICENCE IS NOT VALID WITHOUT AN EMBOSSED SEAL IN THIS BOX



SIGNATURE AND NAME OF ISSUING OFFICER

DAVID HUGHES

CONDITIONS

1. This licence is invalid if amended. If amendments are required - including changes of company name or named individuals- this licence should be returned to Drugs & Firearms Licensing Unit (DFLU) for cancellation and a fresh application submitted.
2. This licence is only valid for the Schedule(s) of drugs and activities as specified above.
3. This licence is only valid for the company and premises specified above. It is not transferable to another company or premises.
4. All individuals named on the licence application must obtain refreshed enhanced DBS checks (in accordance with the provisions in SI 2009/1818) at the required frequency.
5. This licence is only valid until the expiry date above, must be retained for inspection and may be revoked at any time by the Secretary of State.
6. Expired licences cannot be extended. Licensees are responsible for submitting a valid application for a further licence, before the expiry date of this licence, in order to preserve the conditions of the licence whilst a decision is pending on a further licence.
7. If this licence is not used it must be returned to DFLU clearly marked for cancellation.