



Medicines & Healthcare products
Regulatory Agency

[REDACTED]
ROKSHAW LIMITED
UNIT 5A
EAST WAY
RIVERGREEN INDUSTRIAL ESTATE
SUNDERLAND
SR4 6AD
UNITED KINGDOM



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra



MS NUMBER: MS 41467

Version: 15

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 41467

2. Name of Licence Holder

ROKSHAW LIMITED

3. Trading Style

CURALEAF LABORATORIES

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:
19385661	ROKSHAW LIMITED	UNIT 7, EAST WAY, RIVERGREEN INDUSTRIAL ESTATE, SUNDERLAND, SR4 6AD, UNITED KINGDOM

5. Legally registered address of Licence Holder

UNIT 5A, EAST WAY, RIVERGREEN INDUSTRIAL ESTATE, SUNDERLAND, SR4 6AD, 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



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SECTION 1A (continued)

9. Date 17/06/2025

10. Annexes attached

Annex 1

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)



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SECTION 1B

1. This licence is granted in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of these regulations.
2. It authorises the processes of manufacture and/or assembly and/or importation to which Regulation 167 of The Human Medicines Regulations 2012 (SI 2012/1916) applies, of the description or general classification at the premises specified and in accordance with the particulars set out in Section 3 by the licence holder named. All manufacturing operations in respect of those products for which a product licence is required shall be conducted so as to ensure that the products shall conform to the standards of strength, quality and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured or the specification under which the products are sold or supplied.

In relation to such products the licence holder shall either:

- a) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with such specification any tests of the strength, quality or purity as required by that specification or,
 - b) make arrangements with a person approved by the Licensing Authority for such tests to be carried out on his behalf by that person.
3. The operations referred to in Section 3 shall be undertaken by the personnel named therein or by such other person as may be approved by the Licensing Authority.

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



SECTION 1B (continued)

4. The licence holder's arrangement for:

- a) identification and storage of materials and ingredients before and during manufacture and for the storage of medicinal products after manufacture or assembly;
- b) ensuring a satisfactory turnover of stock of medicinal products;
- c) maintaining records of production, of analytical and other testing procedures;
- d) keeping reference samples of materials used in the manufacture of any medicinal products shall be in accordance with the particulars contained in or furnished in connection with the application of this licence, or shall be in accordance with such other arrangements as may from time to time be approved by the Licensing Authority.

5. The licence holder must inform the Licensing Authority in advance of any change to the details submitted or included in this licence. All changes must be approved by the Licensing Authority prior to becoming effective. This includes any changes to named premises, persons, operations processes or structural alterations. If the business should change hands the new company or person must obtain a new licence prior to commencing operations.

6. A licence may be suspended if any fees are not paid in full as they fall due.

7. The Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).

8. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.

9. Licence Structure

This Licence is divided into three sections.

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



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
12/03/2015	Initial Application
12/03/2015	Internal variation to remove Stability testing as requested by the inspector.
16/10/2015	Variation: Remove [REDACTED] as a PM and replace with [REDACTED]
12/01/2016	Internal variation: Add site function (Other non-sterile medicinal products - Pellets)
13/07/2018	Variation: Remove [REDACTED] Add [REDACTED]
03/04/2019	Variation (site 10573410): - update site types to add 'Import' - add 'Solids and implants' (Terminally Sterilised products) - add 'Secondary packaging' - add 'Over labelling of unlicensed imported medicines' under Other Importation Activities
04/04/2019	Internal variation: add manufacture of terminally sterilised products
24/11/2020	Variation to - Add new site 19385661 - [REDACTED] - Add [REDACTED] site 336740 as a contract laboratory.
23/11/2021	Variation to remove [REDACTED] as QC. Add [REDACTED] as QC and site contact for sites 10573410 and 19385661
21/03/2023	Variation to remove [REDACTED] as QC and site contact to sites 10573410 and 19385661. Add [REDACTED] as QC to sites 10573410 and 19385661
26/05/2023	Internal variation to remove [REDACTED] as QC and site contact to site 19385661. Add [REDACTED] as QC to site 19385661
07/09/2023	Internal Variation to: Add Other solid dosage forms, Suppositories, Semi-solids. Remove Solids and implants - site 10573410. Add Manufacture of herbal products to sites



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	10573410 & 19385661
25/09/2023	Internal Variation to: Remove Homeopathic products and add herbal products to sites 10573410 & 19385661
09/04/2025	Variation to remove sites 10573410, 30429, 318192 & 336740. Add [REDACTED] as SC to site 19385661. Add Other non-sterile medicinal products- Liquid for inhalation and Packaging- Liquid for inhalation to site 19385661. Add CURALEAF LABORATORIES as a trading style
17/06/2025	Variation to replace [REDACTED] with [REDACTED] as QC at site 19385661



MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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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:	ROKSHAW LIMITED
ADDRESS:	UNIT 7, EAST WAY, RIVERGREEN INDUSTRIAL ESTATE, SUNDERLAND, SR4 6AD, UNITED KINGDOM
MHRA SITE NUMBER:	19385661

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	<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	Not Authorised



	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products Lozenges, lollipops, reefers, soaps, Liquid for inhalation	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	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	Not Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	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
	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products Liquid for inhalation	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>
		Yes	No
		No	Yes
		No	No
		No	No

Key to Roles:

PM – Production Manager/Supervisor

QC – Person responsible for Quality Control



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ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
19385661	ROKSHAW LIMITED	UNIT 7, EAST WAY, RIVERGREEN INDUSTRIAL ESTATE, SUNDERLAND, SR4 6AD, UNITED KINGDOM