SAHPRA
South African
Health Products
Regulatory Authority

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Kirkness Road
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Enquiries: Jerry Molokwane
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Tel: 076 422 4934
Reference: 0000001401.-.2

The Responsible Pharmacist
Green Engineering Solutions (Pty) Ltd
Unit 1, 121 Capricorn Drive, Capricorn Business and Technology Park
Muizenberg, Cape Town
Western Cape
7948

Tel: 021 180 3097
Email: corne@geslabs.com

Dear Sir/Madam

RE: LICENCE **Amendment (Additional Activities and Change of Key Personnel)** TO ACT AS a **Manufacturer, Importer and Exporter** of Medicines IN TERMS OF SECTION 22C (1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT,1965

Manufacturer, Importer and Exporter Licence: 0000001401.-.2

Your licence to act as **Manufacturer, Importer and Exporter** in terms of section 22C (1)(b) of the Medicines and Related Substances Act has been approved and is attached herewith. This document replaces any licence document previously issued to you.

This licence authorizes the acting as **Manufacturer, Importer and Exporter** by the licence holder named; if the business should change hands, the company or person taking over the business will have to obtain a new licence before commencing acting as a **Manufacturer, Importer and Exporter** of products.

This licence is subject to the limitations specified in the licence and to the statutory provisions contained in the Regulations to the Act.

Activities may only be carried out in accordance with the terms of the relevant product licence, unless a specified exemption applies which allows it to take place other than in accordance with the licence.

The licence relates to the acting as a **Manufacturer, Importer and Exporter** of products on the premises and under the supervision of the persons specified. If any change of premises or of those persons to take place, prior approval must be sought from Licensing Authority. Any proposal to make structural alterations to the premises must also be notified to the Licensing Authority.

The Licensing Authority has power to revoke licences in terms of section 22E should the inspection result in a negative SAHPRA resolution.

Yours faithfully

Digitally Signed by:
JERRY MOLOKWAN

Jerry Molokwane
UNIT MANAGER: PHARMA LICENSING

Date: 07/07/2023 08:18:17 AM

South African Health Products Regulatory Authority

SAHPRA
South African Health Products Regulatory Authority

Licence number: 0000001401.-.2

LICENCE TO MANUFACTURE MEDICINES

In terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965

This licence is granted to:

Licence Holder
Green Engineering Solutions (Pty) Ltd
Unit 1, 121 Capricorn Drive, Capricorn Business and Technology Park, Muizenberg, Cape Town, Western Cape, 7948

On the following terms and conditions:

The licence holder and the persons described and named in Annexure 1 shall at all times ensure that all medicines manufactured in this facility, irrespective of its registration status, comply with all the provisions of the Medicines and Related Substances Act, 1965, as amended and in particular with sections 14, 18, 18A, 18B, 18C, 19, 20, 22A, 22C, 22G, 33, Regulations 7, 10, 11, 12, 13, 14, 15, 40, 42, 53 and all relevant SAHPRA Guidelines.

This facility is authorised to perform the manufacturing activities depicted in Annexure 1 to this licence.

Digitally Signed by:
Boitumelo Semete-Makokotlela
Chief Executive Officer
53e72d92-3391-4cd7-8da3-b6116e65c520
07/07/2023 02:49:11 PM

CHIEF EXECUTIVE OFFICER

ORIGINAL ISSUE DATE: **04 November 2021**
RENEWAL DATE: N/A
FIRST AMENDMENT DATE: **06 July 2023**
EXPIRY DATE: **04 November 2026**

ANNEXURE 1

AUTHORISED MANUFACTURING AND MATERIAL HANDLING ACTIVITIES

1. MANUFACTURING ACTIVITIES	YES	NO
Sterile, Non-biological Manufacture		
Large volume parenteral products		NO
Small volume parenteral products		NO
Other sterile dosage forms: N/A		NO
Non-sterile Manufacture		
Tablets		NO
Capsules		NO
Liquids: **Bulk API containing Cannabinoids including Dronabinol extracted from approved South African Cultivated Cannabis and authorised imported product.** **Dronabinol formulated extract.** **THC formulated extract.** **CBD formulated extract.**	YES	
Semi-solids	YES	
Suppositories		NO
Other non-sterile dosage forms: **CBD isolate, Dronabinol syringes and THC/CBD cartridges**	YES	
Biological Manufacture		
Vaccines		NO
Sera and other immunologicals		NO
Blood and other blood products		NO
Other biological products: N/A		NO
Medical Gas Manufacture		NO
Radioactive Medicines Manufacture		NO
Complementary Medicines Manufacture	YES	
2. PACKAGING ACTIVITIES		
Packaging and labelling of manufactured product	YES	
Re-labelling or redressing	YES	
Cartoning or secondary packaging	YES	
3. TESTING ACTIVITIES		
Analytical	YES	
Microbiological		NO
Sterility		NO
Stability	YES	
Animal		NO
Other Testing Activities:		NO
4. DISTRIBUTION ACTIVITIES		
Bulk distribution as defined in off-take agreements with SAHPRA approved vendors	YES	
Fine distribution as defined in off-take agreements with SAHPRA approved vendors	YES	
5. MATERIALS HANDLED OR STORED AT THIS SITE		
Penicillins (Finished Packed Products Only)		NO
Cephalosporins (Finished Packed Products Only)		NO
Hormones (Finished Packed Products Only)		NO
Cytostatics/Cytotoxics (Finished Packed Products Only)		NO

Bulk Pesticides, Herbicides or Rodenticides (Finished Packed Products Only)		NO
Potent Steroids (Finished Packed Products Only)		NO
Other potent, toxic, sensitising or hazardous materials: – Approved level of THC and CBD in cannabis	YES	
6. IMPORT – Refer site specific conditions	YES	
7. EXPORT – Refer site specific conditions	YES	

8. PARTICULARS OF THE PERSONNEL RESPONSIBLE FOR OPERATION ON THE PREMISES ON BEHALF OF THE LICENCE HOLDER

Responsible Pharmacist	Head of Production	Quality Control Person
Johann Corné Carstens	James De Beer	Melisha Poken
B. Pharm	BSc. Chem, M. Data Science	BSc. Biological Science

9. PARTICULARS OF THE NATURAL PERSON RESPONSIBLE TO THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY TO ENSURE COMPLIANCE WITH THE MEDICINES AND RELATED SUBSTANCES ACT, 1965

Responsible Person	Designation	Residential Address
Peter-William Nel	Managing Director	Unit 1, 121 Capricorn Drive, Capricorn Business and Technology Park, Muizenberg, Cape Town, Western Cape, 7948
B. Eng. (Chemical)		

10. GENERAL LICENCE CONDITIONS:

1. The holder of the licence shall conduct all manufacturing, wholesaling or distribution operations in respect of those medicines for which a registration certificate has been obtained, so as to ensure that the medicines shall conform to the standards of quality, strength and purity applicable to them in accordance with the specifications made by the person to whose order they are manufactured, wholesaled or distributed or the specifications under which the medicines are sold or supplied.
2. Medicine for export for which a registration certificate has not been obtained from the SAHPRA may not be exported without the relevant "Certificate of a Pharmaceutical Product" or alternatively a "Licensing Status of a Pharmaceutical Product" issued by the SAHPRA in terms of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.
3. The manufacturer to comply with cGMP principles.

4. The licence is restricted to activities listed only; any additional activities must be approved by SAHPRA prior to implementation
5. Any critical changes (Refer to S.A. Guideline Amendments) must be approved by SAHPRA prior to implementation.
6. The licence holder does not own a registered/authorised product for marketing or distribution in the South African market
7. The licence holder can only manufacture Scheduled substances on behalf of approved HCR who have authorised or registered products
8. The licence holder will be in possession of relevant permits in terms of Section 22A (9) and 22A(11) of the Medicines and Related Substances Act, 101 of 1965 (Medicines Act)
9. The licence holder will furnish information to SAHPRA as per Section 22A and regulation 28 of the Medicines Act
10. The licence holder will provide SAHPRA with the list of authorised specific Scheduled substances to be manufactured
11. Licence holder must notify SAHPRA of any changes to authorised off take agreements including vendor changes, and those must be approved prior to implementation
12. All vendors i.e. Wholesale, Laboratories or specific category Pharmacy must be in possession of a valid SAHPRA licence and any other applicable legislation registration
13. Licence holder will only export scheduled substance that are approved by SAHPRA

11. ADDITIONAL LICENCE SPECIFIC CONDITIONS (IF REQUIRED)

GENERAL CONDITIONS:

- The site to comply with cGMP principles.
- The Approval is restricted to activities listed only; any additional activities must be approved by SAHPRA prior to implementation, and
- That any critical changes (Refer to S.A. Guideline Amendments) to the facility be approved by SAHPRA prior to implementation.
- The company should use only the positive resolution to apply for granting or re-granting of the licence as specified above. As an addition, if there was not a routine inspection as stipulated in this resolution, the company is required to request an inspection at least 180 days prior to the expiration of the licence.

SITE SPECIFIC CONDITIONS:

- The manufacturer to respond on the defined time commitments of outstanding deficiencies.
- Effective implementation of several corrective actions to be verified during the next inspection.
- The facility is authorised to import CBD isolate and full-spectrum cannabis oil.
- The licence prohibits importation of the cannabis biomass
- The facility is authorised to export Dronabinol formulated extract, THC/CBD formulated extract, Dronabinol syringes and THC/CBD cartridges.

- The company is required to have the control systems in place for Import and Export which will be verified at next inspection

DOCUMENT HISTORY:

REVISION	REASON FOR AMENDMENT	DATE
1	First issue of Licence	04 November 2021
2	First issue of Licence Amendment (Additional Activities and Change in Key Personnel)	06 July 2023