LICENCE APPLICATION TO CULTIVATE, MANUFACTURE OR IMPORT CANNABIS FOR MEDICINAL PURPOSES

- An application form for the purpose of **obtaining** a licence **or renewing** a licence in terms of the provisions of the Medicines and Related Substance Act, 1965 Section 22C and 22D to be read in conjunction with Regulation 23 and 24 of the Act.

- This form should be completed by or for each manufacturer of Cannabis who is not exempted from the requirement to hold a licence and who wishes to cultivate, manufacture or import or who wishes to renew their existing licence to cultivate, manufacture or import.

- Incomplete forms may be returned to the Applicant. Please type or print in black ink. Any alterations must be initialled and dated. Application forms with white out will be returned. All required copies of certificates should be certified.

- The prescribed application fee or proof of payment for a licence must accompany the licence application forms. For amount, refer to the fees payable as published in the Government Gazette and published on the SAHPRA website, also available from the office of the CEO of SAHPRA.

  Note: Cheques should be made payable to **"South African Health Products Regulatory Authority"**

- The completed form should be emailed to:

  gmplicensing@sahpra.org.za

- The licence is the property of the South African Health Products Regulatory Authority (SAHPRA)and must be returned upon demand. The licence remains valid for the period of five years from the date of issue unless otherwise suspended or revoked by the South African Health Products Regulatory Authority (SAHPRA).

- Licensing guidelines are available at the SAHPRA's website: https://www.sahpra.org.za/

- After five years the Applicants licensed to cultivate, manufacture, import or export, as the case may be, need to renew their licence.

Guidance Notes & General information

Definitions and Acronyms

DALRRD – Department of Agriculture, Land Reform and Rural Development

GAP – Good Agricultural Practices

GMP – Good Manufacturing Practices

SAHPRA – South African Health Products Regulatory Authority

Name of the proposed licence holder

Full, legal name of licence applicant or owner of the business who wishes to cultivate, manufacture or import (must be a full, *legally identifiable name* e.g. 'ABC Pty Ltd', 'Newcorp Ltd' trading as XYZ', 'Gillian Linda Smith trading as MNR). Spaces are provided for the following options. Please insert as applicable.

a) Name if sole individual trader

   The individual's full name if trading as an individual trader

b) Name of corporation or company

   If a corporation or company, the name of the registered corporation or company under the Companies Act and the **registration number** allocated by the Registrar of Companies.

c) Name if trading under other business name

   The business name, or name under which you propose to trade for purposes of the Act [if different from (a) or (b)]

Declaration

This declaration seeks assurances that the requirements of Section 22C and 22D and Regulation 23 and 24 of the Act, as the case may be, have been satisfied and that the information provided in the application is current and correct at the time it was signed by the cultivator, manufacturer or importer. The declaration in A (iii) is intended to establish whether a manufacturer has received a notice that its manufacturing operations do not comply with current acceptable quality assurance principles and good manufacturing practices as determined by the South African Health Products Regulatory Authority. A penalty applies for false and misleading statements made in relation to this application.

Persons signing the declaration

Persons signing the declaration should be the cultivator, the manufacturer, or the cultivator/manufacturer's duly appointed designee who is responsible to the South African Health Products Regulatory Authority (SAHPRA)for compliance with the Act – refer Regulation 23 (1)(c)(iii).

Name	Full name
Position	The role in the organization e.g. Owner, Designee.

Site Master File

Part of the reporting aspects of the audit can be addressed by receiving information on related company details, e.g. details of the company's facilities, personnel structure and operating procedures including manufacturing activities, prior to audit.

It is expected that a Site Master File be prepared and submitted to the Law Enforcement that should be in line with the guidelines on the preparation of a Site Master File, which can be obtained from the office of the CEO of

SAHPRA or the South African Health Products Regulatory Authority (SAHPRA)website at: https://www.sahpra.org.za/

Date of audit

Before a licence may be issued or renewed, the Law Enforcement/Regulatory Compliance will conduct an audit of the company's growing or manufacturing operations to assess conformity with the GAP and GMP as determined by the DAFF and SAHPRA respectively. In order to schedule an audit the applicant should indicate an approximate date by which they will be ready for an audit. If this date changes after the application is submitted the Law Enforcement should be notified as soon as possible. The inspector/s assigned to undertake the audit will advise the manufacturer of the actual date of the audit approximately five working days beforehand.

Good Agricultural Practices

The GAP in South Africa is a set of practices that addresses environmental, economic and social sustainability for on-farm processes and result in safe and quality of agricultural products.

Good Manufacturing Practices

Pursuant to the current GMP Guidelines the Authority may determine written principles to be observed by a cultivator or manufacturer of Cannabis. These principles will primarily comprise the Guidelines on Good Manufacturing Practice. A copy of the current guidelines on GMP may be obtained by the manufacturer of medicines, biologicals or medical gas products from the office of the CEO of SAHPRA or the website of the South African Health Products Regulatory Authority (SAHPRA): https://www.sahpra.org.za/

Responsible Pharmacist

Responsible Pharmacist (RP) means a natural person who is a pharmacist and who is responsible to the South African Pharmacy Council for complying with all the provisions of the Pharmacy Act and other legislation applicable to services that specially pertain to the scope of practice of a pharmacist.

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Note: If any of the details contained in this Application Form should change after this document has been signed, the Applicant will be obliged to submit an updated application form within 30 days, otherwise the Licence will automatically become null and void.

PART A: GENERAL INFORMATION

1.1 APPLICATION TYPE			
☐	New		
☐	Renew	SAHPRA Licence Number:	

1.2 APPLICANT DETAILS	
Title	
Full Name	
Telephone Number (Office)	
Mobile Number	
Fax Number	
E-Mail Address	

1.3 BUSINESS REGISTRATIONS		
1.3.1	Is the business registered with the SAHPRA as a Manufacturing Facility?	☐ Yes ☐ No
1.3.2	Is the business registered with the National Department of Agriculture, Land Reform and Rural as a Farming Facility?	☐ Yes ☐ No

2.1 BUSINESS DETAILS	
Name of individual / owner	
Registered Company Name (if Corporation)	
Trading Name (if applicable)	
Company or Corporation Registration number issued by Registrar of Companies	

2.2 ADDRESS FOR COMMUNICATIONS	
Line 1	
Line 2	
Town/ City	
Province	
Postal code	

PART B: SITE INFORMATION

Note: Separate forms must be completed for each site where cultivation, manufacturing and/or packaging activities take place.

3.1 SITE DETAILS	
Site Name	
Has this site previously held any licence under the Act?	☐ Yes (**Note:** If yes, please attach details) ☐ No
3.2 SITE ADDRESS	
Line 1	
Line 2	
Town/ City	
Province	
Postal code	
3.3 SITE LOCATION COORDINATES	
Coordinates required for Cultivation purposes only	
3.4 DOCUMENTS ENCLOSED	
Property Owners (if application)	☐ Yes ☐ No
Police clearance documents of business owner	☐ Yes ☐ No
3.5 SITE MASTER FILE (SMF)	
Note: Before a licence audit is conducted, manufacturers are required to submit a Site Master File. A SMF previously submitted must not be older than **2 years**.	
Is the SMF enclosed?	☐ Yes ☐ No
Has the SMF been submitted before?	☐ Yes ☐ No
SMF number (if known)	

4 SITE CONTACT (RESPONSIBLE PERSON)	
Title	
Full Name	
Identity number	
South African Pharmacy Council Reg. No.	
Telephone Number	
Mobile Number	
Fax Number	
E-mail address	

5 SITE USAGE
Describe below any other activities on this site which are <u>not</u> connected with medicine.

6 ACTIVITIES AT SITE
If the Licence is for **packaging only**, go to section B3. Please tick: **C** for (cultivation) or **MP** (Manufacture, Testing and Packaging) or **M** (Manufacture and Testing only) as appropriate for each category of production below.

A	CULTIVATION (Provide details in the Site Masterfile)	
A1.1	Types of seeds	
A1.2	The area for growing (m^2)	

B	MANUFACTURING (Provide details in the Site Masterfile)		C	MP	M
B1.1	**Unit and multi dose liquids**				
B1.1.1	Internal				
B1.1.2	External				
B1.1.3	Aerosols (pressurised)				
B1.2	**Semi-solid & other liquid dosage forms** Please specify below				
B1.3	**Solid dosage forms**				
B1.3.1	**Unit dose forms:**	Tablets			
		Capsules, hard gelatin			
		Capsules, soft gelatin			
		Suppositories/pessaries			
B1.3.2	**Multi-dose forms (including powders and granules)**				
B1.3.3	**Other solid non-sterile dosage forms** Please specify below				
B1.4	**Other dosage forms**				
	Veterinary premixes/ feed mills				

C	PACKAGING ONLY (Provide details in the Site Masterfile)	
Filling of sterile products is classified as manufacturing, not as packaging. Please tick the appropriate boxes.		
C1	**Packaging activities**	**P**
C1.1	Filling of primary containers	
C1.2	Labelling of primary containers	
C1.3	Liquid dosage forms	
C1.4	Semi-solid dosage forms (including creams and ointments)	
C1.5	Solid dosage forms (including tablets and powders)	
C1.6	Other dosage forms, please specify below	

7	ANALYTICAL TESTING SITES (Provide details in the Site Masterfile)	
This refers to the site(s) at which analysis or testing of starting materials, packaging materials, intermediate, bulk and finished products take place. This may also include one or more of the sites where manufacturing and/or packaging takes place.		
7.1	**Site name**	
7.2	**Site address**	
	Line 1	
	Line 2	
	Town/ City	
	Province	
	Postal code	
7.3	**TESTING ACTIVITIES AT THIS SITE**	
Please tick the appropriate boxes.		
D1	Chemical/ physical	
D2	Microbiological/ sterility/ environmental/ LAL	
D3	Pyrogens (rabbit test method)	
D4	Stability testing	
D5	Other, please specify	

8 STORAGE AND HANDLING OF HARVEST MATERIALS (Provide details in the Site Masterfile)	
8.1 SITE NAME	
8.2 SITE ADDRESS	
Line 1	
Line 2	
Town/ City	
Province	
Postal code	
8.3 SITE CONTACT PERSON	
Title	
Full name	
Telephone number	
Mobile number	
Fax number	
E-mail address	
8.4 SITE USAGE	
Is this site used for distribution only (i.e. onward dispatch of ready packed orders)?	☐ Yes ☐ No
OR Is this site used for other purposes?	☐ Yes ☐ No
If used for other purposes, please specify below	
8.5 EQUIPMENT AND FACILITIES ON SITE	
Is a description of facilities available for the storage and distribution of medicinal products detailed in the Site Master File?	☐ Yes ☐ No
Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File?	☐ Yes ☐ No
If these descriptions are not included in the SMF, please provide brief descriptions (approximately 500 words each) of the facilities available and the equipment available for the storage and distribution of medicinal products on a separate sheet of paper.	
8.6 ACTIVITIES RELATING TO IMPORT/EXPORT	
Are medicines imported/exported by the Applicant?	☐ Yes ☐ No
If yes, please provide a list of products being imported/exported.	

9 STORAGE AND HANDLING OF FINISHED PRODUCT MATERIALS (Provide details in the Site Masterfile)	
9.1 SITE NAME	
9.2 SITE ADDRESS	
Line 1	
Line 2	
Town/ City	
Province	
Postal code	
9.3 SITE CONTACT PERSON	
Title	
Full name	
Telephone number	
Mobile number	
Fax number	
E-mail address	
9.4 SITE USAGE	
Is this site used for distribution only (i.e. onward dispatch of ready packed orders)?	☐ Yes ☐ No
OR Is this site used for other purposes?	☐ Yes ☐ No
If used for other purposes, please specify below	
9.5 EQUIPMENT AND FACILITIES ON SITE	
Is a description of facilities available for the storage and distribution of medicinal products detailed in the Site Master File?	☐ Yes ☐ No
Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File?	☐ Yes ☐ No
If these descriptions are not included in the SMF, please provide brief descriptions (approximately 500 words each) of the facilities available and the equipment available for the storage and distribution of medicinal products on a separate sheet of paper.	
9.6 ACTIVITIES RELATING TO IMPORT/EXPORT	
Are medicines imported/exported by the Applicant?	☐ Yes ☐ No
If yes, please provide a list of products being imported/exported.	

PART C: LIST OF ACTIVITIES

10. Please specify the list of activities to be performed at this site in accordance with the following matrix. ***Note:*** *The entire matrix will be included on the actual licence that will be issued.*

		YES	NO
10.1	**CULTIVATION ACTIVITIES**		
	Storage of seeds		
	Growing of seeds		
	Seeds and Labelling Material		
	Cultivation		
	Harvesting		
	Primary Processing		
	Drying		
10.2	**MANUFACTURING ACTIVITIES**		
	Sterile manufacturing (includes filling, but not cartoning or labelling)		
	Large volume parenteral products		
	Small volume parenteral products		
	Other sterile dosage forms (please specify)		
	Non-sterile Manufacturing		
	Tablets		
	Capsules		
	Liquids		
	Semi-solids (Creams or ointments)		
	Suppositories		
	Other non-sterile dosage forms (please specify)		
	Complementary Medicines Manufacturing		
10.3	**PACKAGING ACTIVITIES**		
	Packaging of bulk product and labelling		
	Re-labelling or redressing		
	Cartoning or secondary packaging		
10.4	**TESTING ACTIVITIES**		
	Analytical		

	Microbiological		
	Sterility		
	Stability		
	Animal		
	Other (please specify)		
10.5	**DISTRIBUTION ACTIVITIES**		
	Bulk distribution to wholesale pharmacies		
	Fine distribution to retail pharmacies and other clients		
	Import		
	Export (please specify products exported on a separate list)		

PART D: PERSONNEL INFORMATION

Guidance notes on nomination of responsible personnel

The Medicines and Related Substance Act, 1965

The Act requires that the applicant shall identify the persons who will have and maintain control of the cultivation, manufacture or import medicinal Cannabis. The Regulations to the Act require that changes be notified promptly to the South African Health Products Regulatory Authority.

Relevant Qualifications for Manufacturing

Relevant qualifications are those relevant to the manufacture of medicines and scheduled substances including those in related sciences and management.

Relevant Experience

Relevant experience is that relevant to the manufacture (including quality management) of medicines and scheduled substances involving comparable good manufacturing practice or experience, which the applicant believes should be taken into consideration as relevant.
All applications should include a relevant CV and each pharmacist nomination shall include a letter of appointment by the licence holder and a letter of acceptance.

11 THE RESPONSIBLE PERSON

Please give the following details of the pharmacist who is to control the manufacture or import of medicinal Cannabis in terms of the provisions of Regulation 23 of the Act. Please submit a certified copy of the candidate's Registration Certificate from the SA Pharmacy Council with this application.

11.1 PERSONAL INFORMATION

Surname	
First Name	
Position in company	
Qualification	
SAPC Registration number	

11.2 RELEVANT QUALIFICATIONS

Degree/ Diploma	Field of study	Institution	Year graduated

11.3 RELEVANT EXPERIENCE (last job first)

Employer	No. of years	Position held

11.4 BUSINESS ADDRESS AND PHONE NUMBER	
Line 1	
Town/ City	
Province	
Postal code	
Telephone number	

11.5 NOMINATION OF RESPONSIBLE PHARMACIST	
I confirm that the above particulars are to the best of my knowledge and belief accurate and true. I agree to be nominated as the Pharmacist responsible for the manufacture or import of medicinal Cannabis substances as detailed in this licence application.	
Name (Responsible pharmacist):	
Signed	Date:
Name (designee)	
Signed (designee)	Date:

12 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF PRODUCTION	
12.1 PERSONAL INFORMATION	
Surname	
First Name	
Position in company	

12.2 RELEVANT QUALIFICATIONS			
Degree/ Diploma	Field of study	Institution	Year graduated

12.3 RELEVANT EXPERIENCE (last job first)		
Employer	No. of years	Position held

13 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF QUALITY CONTROL/ASSURANCE	
13.1 PERSONAL INFORMATION	
Surname	
First Name	
Position in company	

13.2 RELEVANT QUALIFICATIONS			
Degree/ Diploma	Field of study	Institution	Year graduated

13.3 RELEVANT EXPERIENCE (last job first)		
Employer	No. of years	Position held

14 PERSON(S) RESPONSIBLE FOR SECURITY	
14.1 PERSONAL INFORMATION	
Surname	
First Name	
Position in company	

14.2 RELEVANT QUALIFICATIONS			
Degree/ Diploma	Field of study	Institution	Year graduated

14.3 RELEVANT EXPERIENCE (last job first)		
Employer	No. of years	Position held

14.4 NAME AND FUNCTION TO WHOM HE/SHE REPORTS

15 PROPOSED DATE OF AUDIT

PART E: DECLARATION

Applicants should note that in terms of the provisions of the Medicines and Relates Substances Act, 1965 it is an offence to make false claims and misleading statements in connection with an application for a licence to manufacture, import or export medicine or scheduled substances.

A.	**I declare that:** (Tick one box only in each case)	**YES**	**NO**
(i)	The applicant had a licence revoked after being granted such a licence.		
(ii)	The applicant has been convicted of an offence against the Medicines and Related Substances Act, 1965 or a law of a state or territory relating to medicines and related substances.		
(iii)	The applicant has been convicted of an offence against use or dealings in illicit drugs.		
(iv)	The information provided in this application is current and correct.		

If parts (i), (ii) or (iii) of the declaration were answered in the affirmative, details should be provided on additional pages.

B. **I/ We** apply for the **new/ renewal** (indicate by crossing out the non-applicable section) of a Manufacturer's Licence to the proposed holder name in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Cultivator / Manufacturer's Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965.
2. The cultivation, manufacturing or import operations are conducted only in accordance with the information set out in the application or furnished in connection with it.
3. I / We declare that we hold the relevant product registrations or are named on the relevant product registrations as cultivators or importers or manufacturers and / or packaging relating to the Cannabis products we wish to cultivate or import or manufacture and / or pack pursuant to this application.
4. To the best of my / our knowledge and belief the particulars I / we have given in this form are correct and complete.

The above declaration must be signed as follows:

- in the case of a corporation or company: by the designee / natural person who shall be responsible to the Authority for compliance with the Act.
- in the case of other enterprises: by the owner.

Full Name	
Signature	
Position within organisation	
Date	

Note: *This is a legal document. Any changes to the application once submitted must be made in writing detailing the requested variation and be signed by the authorised person above.*