CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) for ACTIVE PHARMACEUTICAL SUBSTANCES

SAHPRA
South African Health Products Regulatory Authority

Written confirmation for active substances exported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC
Confirmation no: **API26/7/3/3/1 / G0039/2023**

1. *Name of Site (including building number, where applicable):* ***Farma Growers Group (Pty) Ltd***
   Address: **KleinFontein District Brits, Brits, North West, 0250.**
2. *Manufacturer's license number (Cultivation)*: **0000000019MC - v1**

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s) (INN name):	Activity(ies):[1]
Tetrahydrocannabinol (THC) & Cannabidiol (CBD) – Contained in cannabis dried flower.	**Cultivation, trimming, drying and packaging**

THE CHIEF EXECUTIVE OFFICER OF SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY OF THE REPUBLIC OF SOUTH AFRICA, HEREBY CONFIRMS THAT:
The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (=GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the Chief Executive Officer of South African Health Products Regulatory Authority, -of South Africa without delay to the EU at email: *qdefect@ema.europa.eu*

3. *Date of the inspection of the plant under (1):* ***18th September 2020***
4. *Name of the inspecting authority if different from the issuing regulatory authority:* **SAHPRA**
5. *This written confirmation remains valid until:* ***31 May 2024***

The authenticity of this written confirmation may be verified with the Chief Executive Officer of South African Health Products Regulatory Authority, of South Africa.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC

Address of the issuing regulatory authority:
THE CHIEF EXECUTIVE OFFICER OF SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY, OF THE REPUBLIC OF SOUTH AFRICA AT BUILDING A, LOFTUS PARK, 2ND FLOOR, KIRKNESS ROAD, ARCADIA, PRETORIA, 0083, RSA

Name and function of the responsible person: **Mr Deon Poovan, Senior Manager: Inspectorate and Regulatory Compliance**
E-mail: **deon.poovan@sahpra.org.za** *Telephone no.* **027 (0) 12 501 0419**

SIGNATURE
DATE: 2023/05/31

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[1] Activities: example: "Chemical synthesis, Extraction from natural sources, Biological processes, Finishing steps"

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA)
The Chief Executive Officer
CSIR Campus, SAHPRA Reception, Building 38, Meiring Naude Drive, Brummeria, Pretoria, 0184
Enquiries: Ms Daphney Fafudi
Tel: 0663011878
Reference: CA000122/18092020

The Responsible Pharmacist/ Person
Farma Growers Group (Pty) Ltd
KleinFontein
Brits
North West
0250

Mobile: +27 82 854 5110
Email: info@farmagrowers.co.za

Dear Ananri Visser
Cc: Mr Mario Marais

SAHPRA RESOLUTION: INSPECTIONS IN TERMS OF SECTION 2B(e) OF THE MEDICINES ACT AND REGULATION 45 THE REGULATIONS: FARMA GROWERS GROUP (PTY) LTD

The inspection, inspection report and your subsequent responses relating to the application for cultivation of medicinal cannabis from Farma Growers Group (Pty) Ltd where Ms Daphney Fafudi and Ms. Grethel Larren conducted an inspection on 18 September 2020 refers.

Authority resolved that:

GACP Status: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, performed on above-mentioned and reflected in the observations listed in the inspection report, and the company responses, the Authority is satisfied that the Farma Growers Group (Pty) Ltd, is operating at an acceptable level of compliance with the principles and guidelines of cultivation of medicinal cannabis. In addition to the aforementioned, the following conditions apply.

GENERAL CONDITIONS: Farma Growers Group (Pty) Ltd:

- **be issued with the Licence for cultivation of medicinal cannabis;**
- **must comply with cGAP principles;**
- **must ensure that there will be no critical changes to the facility prior to approval by SAHPRA;**
- **the cultivation area is limited to the areas inspected;**
- **this is limited to cultivation activities with the harvest material as the end product (no processing of the harvest material to produce finished products is allowed);**
- **Farma Growers Group (Pty) Ltdmust provide on a quarterly basis, the production reconciliation reports; and**
- **Farma Growers Group (Pty) Ltd must submit the annual reconciliation report on the production yields, which contains the substance THC, and CBD.**

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SAHPRA RESOLUTION: INSPECTIONS IN TERMS OF SECTION 2B(E) OF THE MEDICINES ACT AND REGULATION 45 THE REGULATIONS: THUSANANG ENABLING SUPPORT SERVICES (PTY) LTD

SAHPRA RESOLUTION BASED ON APPLICATION SUBMISSION AND INSPECTION CONDUCTED IN TERMS OF SECTION 2B(e) OF THE MEDICINES ACT AND REGULATION 45 THE REGULATIONS: FARMA GROWERS GROUP (PTY) LTD

The resolution reflects the status of **Farma Growers Group (Pty) Ltd** at the time of inspection and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of this letter.

Yours faithfully

DocuSigned by:
Boitumelo Semete-Makokotlela
E2EBB277730A46A...

Dr Boitumelo Semete-Makokotlela

SAHPRA CEO

DATE:

For purposes of this communication, unless otherwise indicated:

"Medicines Act" refers to the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended;

"Regulations" refers to the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended; and
"SAHPRA" refers to the South African Health Products Regulatory Authority.

SAHPRA RESOLUTION: INSPECTIONS IN TERMS OF SECTION 2B(e) OF THE MEDICINES ACT AND REGULATION 45 THE REGULATIONS: THUSANANG ENABLING SUPPORT SERVICES (PTY) LTD