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

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/G0108/2023**

1. *Name of Site (including building number, where applicable):* **Green Engineering Solutions (Pty) Ltd**
   Address: **121 Capricorn Drive, Capricorn Park, Muizenberg, Western Cape, 7948**
2. *Manufacturer's license number*: **0000001401**

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.	**Exporting and Manufacturing API liquids containing Cannabinoids extracts and CBD isolates including Dronabinol extracts, Dronabinol formulated extract, THC/CBD formulated extract, CBD isolates, Dronabinol syringes and THC/CBD cartridges**

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):* **01st – 03rd August 2022**
4. *Name of the inspecting authority if different from the issuing regulatory authority:* **SAHPRA**
5. *This written confirmation remains valid until:* **01st August 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: 2023/08/01

SAHPRA South African Health Products Regulatory Authority REPUBLIC OF SA

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