

Communication to Industry – GMP Certificates

09 March 21

GMP CERTIFICATES FOR CANNABIS CULTIVATED BY CULTIVATORS HOLDING A SECTION 22C(1)(b) LICENCE (LICENCE TO CULTIVATE CANNABIS FOR THE PURPOSES OF PRODUCING SCHEDULED SUBSTANCES)

Applicants who are in possession of a Licence to Cultivate Cannabis for Purposes of Producing Scheduled Substances in terms of section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) may apply for a GMP certificate for their facility.

SAHPRA inspections are conducted according to the requirements of the South African guideline “Guideline for Cultivation of Cannabis and Manufacture of Cannabis-Related Pharmaceutical Products for Medicinal and Research Purposes”, which requires licence holders to comply with the SA Guide to Good Manufacturing Practice, which refers to:

- PIC/S Guide to Good Manufacturing Practice for Medicinal Products – Part I for pharmaceutical products
- PIC/S Guide to Good Manufacturing Practice for Medicinal Products – Part II for manufacturing of APIs

N.B The GMP Certificate will be limited to only the following related activities in accordance with the licence issued.

CULTIVATION AND PROCESSING ACTIVITIES ALLOWED
Cloning / Seedling
Vegetation
Flowering
Harvesting
Trimming
Drying
Packaging – (Bulk only)

Licence holders may apply for a GMP certificate by submitting the following documents by e-mail to gmplicensing@sahpra.org.za

- Cover Letter – including purpose of application, list of supporting documents and details of proof of payment
- SAHPRA Licence
- SAHPRA Resolution Letter
- Proof of Payment (as per the gazetted fees)

For enquiries, please contact Mr Bafana Malaza via e-mail at bafana.malaza@sahpra.org.za or Ms Ella Tshabangu at ella.tshabangu@sahpra.org.za

SAHPRA will evaluate whether the conditions of the licenced facility meet the GMP standards as relevant for the cultivation of cannabis, as approval was granted prior to commencement of cultivation activities.

SAHPRA aims to evaluate and finalise the application within 30 working days.

SAHPRA may conduct an inspection to verify compliance to required standards.

Yours faithfully

DocuSigned by:

Deon Poovan

09 March 2021

Senior Manager: Inspectorate and Regulatory Compliance