Plandaí Biotechnology
South Africa (Pty) Limited

9 Palm Street
White River
Mpumalanga, 1240, South Africa

SITE MASTER FILE

THE CULTIVATION OF LIVE CANNABIS PLANTS & THE MANUFACTURE OF PHYTOFARE® CANNABINOID COMPLEXES FOR MEDICINAL RESEARCH PURPOSES

EDITION Ver 2.0
Prepared: January 31, 2018

This document sets forth the security and standard operating procedures relating to the cultivation, manufacture and use of Cannabis and related pharmaceutical products for medicinal and research purposes in South Africa.

C.1. GENERAL INFORMATION

C.1.1. Brief information on the firm (including name and address), relation to other sites and, particularly, any information relevant to understand the manufacturing or wholesaling operations.

This guideline is prepared to outline the company's overall strategy with respect to operations, management and quality control. This Site Master File is to be read in conjunction with the Standard Operating Procedures Manual and the Quality System Manual.

In early 2017, the Company acquired a license from Plandaí Biotechnology, Inc., a USA affiliated party, to conduct research and development and manufacture a cannabis-based extract using a proprietary system developed by Plandaí over the previous fifteen years. A similar commercial processing and extraction system is presently operating on the Senteeko Tea Estate in Mpumalanga, South Africa, where a unique green-tea catechin extract (Phytofare®) is produced and sold to customers around the world. The processing and extraction sciences engineered on Senteeko are unlike any other extraction processes where it relies on live plant material and through the sciences of cavitation and sonochemistry releases and allows for the recovery of the essential plant phytonutrients. The resultant extracts have been clinically validated in both human and animal investigations and have been determined to possess unique physical characteristics through high bioavailability and with pharmaceutical grade composition.

The new Plandai processing and extraction technologies have been redesigned to process oil based live plants and from which to recover both the oil and antioxidants as separate commodities. Unlike conventional cannabis extraction systems that use "super- critical extraction", steam and/or solvents to isolate the oil and cannabinoids, the Plandaí process is temperature controlled and solvent free. As a result, the natural structures of the plant chemicals are not metabolized during either the processing or extraction cycles. For cannabis medicines, this means that the acid forms THC-A is not converted into the psychoactive metabolite THC (*American Herbal Pharmacopoeia Cannabis Inflorescence 2013 Page 34* - attached).

This updated business model will allow Plandaí to produce a pharmaceutical-grade cannabis extract that contains the entire plant chemical profile and without any psychotropic properties. Furthermore, Phytofare® cannabinoid complex is expected to contain medicinal benefits of the full cannabinoid spectrum including cannabinoid acids, terpenes and polyphenols.

Plandaí have engaged the expertise of Nexus group, Northglenn, Colorado to turnkey engineer the latest design in research facilities and cannabis growing knowledge that will meet the South African standards and construction requirements. It is proposed to retrofit an approved Nexus research greenhouse inside the secure Coega facilities that incorporates all the agro husbandry requirements from seed to harvest of the cannabis plant and will include an integrated climate control system providing customized heating, cooling, shade, ventilation and screening systems.

The research and development facility is to be located in the pharmaceutical section of the Coega Development Centre Port Elizabeth, South Africa. This decision will allow the company to successfully complete the research and development phases and then commercially expand into the trade free zone within the Coega facilities.

Research and development protocols are to establish the production of a repeatable chemical profile of its cannabinoid complex that includes both dosage and bioavailability and without psychotropic properties. Upon the successful outcome of these studies, pharmaceutical validation includes initial

in-vitro and mouse-model studies to establish anti-inflammatory activities in the dampening key cells involved in OA and RA. Ultimately prior published in vitro investigations have determined the anti-inflammatory activities of cannabinoids in suppressing inflammation and thereby slowing degradation of affected joints and reducing pain and disability.

Plandaí is currently engaged in securing pharmaceutical facilities at Zone 7, Coega IDZ, Port Elizabeth, 6100, that will provide an MCC approved infrastructure to undertake the research and development requirement. The secure building comprises of 2,249m^2, completely enclosed, and with the necessary security and operational requirements. The building is of concrete block construction with a steel roof and a secure perimeter fencing and guard house

C.1.2 . Pharmaceutical manufacturing or wholesaling activities as licensed or approved by the Competent Authorities.

Plandaí will initially conduct research and development. The company will not operate any licensed or approved manufacturing or wholesaling activities outside of these disciplines. Activities to be carried out, and as set forth in Section C.1.1, above, will operate under license from the Medicine Control Counsel.

1.3. Any other manufacturing or wholesaling activities, as the case may be, carried out on the site.

Activities at the Site will include cannabis cultivation, extraction, disposal, and storage. All operations will be conducted in a "closed room" environment and be consistent with that of any indoor hydroponic agriculture operation. The extraction system consists of a proprietary cavitation chamber, filtration, water removal, and evaporation system. Finished product will be hermitically sealed and stored on site. All waste will be sterilized and either incinerated or composted.

There will be no wholesale, retail or other sales activities at the site. All product manufactured will be for scientific research purposes only.

C.1.4. Name and exact address of the site, including telephone, fax and 24 hrs telephone numbers.

Coega IDZ Business Center
Zone 7
Coega IDZ
Port Elizabeth, 6100

GPS Coordinates: 43^0 45' 42.62''^{I} S
25^0 42' 10.13'' E

Telephone and fax numbers have not yet been established. The contact person for this facility is Roger Baylis Duffield, phone number +27 (72) 163-6099.

C.1.5. Type of actual products manufactured on the site (see list at Appendix), or list of products wholesaled on site (as the case may be) and information about specifically toxic or hazardous substances handled, mentioning the way they are manufactured (in dedicated facilities or on a campaign basis) or in the case of a wholesaler (any special precautions taken for storage or distribution).

The company will produce Phytofare® Cannabinoid complex in a hygroscopic powder form and will separately recover Phytofare® cannabis oil, that will be denuded of salt and highly bioavailable containing Omega 3 and 6 fatty acids.

There are no toxic or hazardous substances used in the manufacture or extraction process. Cultivation and propagation activities use standard formulated industrial fertilizers, plant food and water. As the growing chambers are fully enclosed incorporating sub-micron air filters, the use of herbicides and pesticides are not contemplated at present. The extraction process utilizes only water.

The extraction and storage operations will be conducted on site but in an area of the facility separate from the growing and propagation activities. As with other areas of the facility, the storage area will be climate and temperature controlled in order to optimize the longevity of stored product.

C.1.6. Short description of the site (size. location and immediate environment and other manufacturing or wholesaling activities, as the case may be, on the site).

The facility is located within Zone 7 of the Coega Industrial Development Zone in Port Elizabeth, an area dedicated to pharmaceutical operations. No other activates apart from that of Plandaí will take place within the immediate confines of the designated building.

The building encompasses a single story measuring 2,249m^2 of space under roof. The building is new construction (within 5 years), never occupied, and constructed of masonry with a metal roof and poured concrete floors.

C.1.7. Number of employees engaged in the quality assurance, production, quality control, storage and distribution as the case may be.

There are no employees as of this submission. The total number of employees will be fewer than ten. Employee candidates will be rejected, or terminated following hiring, for any of the following:

- is under the age of 18 years
- has been convicted of a serious offence
- has a drug addiction, or undertaking, or has undertaken, treatment for drug addiction
- has a history of illicit drug use or a conviction for an illicit drug-related offence
- fails a drug screen

The Company estimates that employees will be categorized as follows:

• Admin	2
• Security	3
• Growing and propagation	3
• Processing and Extraction	2
• Maintenance	1
• Pharmacist	1
Total projected employees	12

C.1.8. Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis; and in the case of a wholesaler any outside scientific, analytical or other technical assistance relating to any wholesaling activities if applicable.

No outside scientific, analytical or other technical assistance will be performed on site. The following analytical tests will be performed by Labserve Analytical Services, Nebo Park, Suikerriet Street, Nelspruit 1200 (www.labserve.net) on every batch of extract produced:

- Appearance
- Foreign Material
- Fineness
- Identification A: Microscopic Properties
- Identification B: TLC
- Microbiological Contamination
- Aflatoxins
- Pesticides
- Heavy Metals
- Assay and Related Substances
- Chemical profile

C.1.9. Short description of the quality management system of the firm responsible for manufacture or wholesaling, as the case may be.

C.1.9.1. Quality Policy.
Senior management is dedicated to providing the resources necessary to maintain the quality management system and to ensure the facility's participation in the institutional quality plan. The Company is committed to continual improvement, meeting internal requirements and customer requirements, and providing a basis for the establishment and review of the quality objectives. Quality practices are communicated within the organization, understood and adhered to by all employees. The Company ensures a competent workforce to deliver quality results in a timely manner according to the ISO 9001 standard.

C.1.9.2. The responsibility of the Quality Assurance function.
The Company has adopted a detailed Quality Assurance protocol that governs all aspects of operations to ensure that the Standard Operating Procedures are being complied with and that results (output) is consistent.

The objectives of the QA process, as defined in the manual are as follows:

> "The objectives of the facility are to produce a chemically consistent extract of pharmaceutical-grade purity and reliability to ensure optimal and reproducible clinical results, achieve and maintain an effective quality management system and ensure compliance with relevant statutory and safety requirements. The quality committee, through the quality manager, contributes to the implementation of the quality management system to achieve the defined objectives."

C.1.9.3. Elements of the QA system;

Organization – This section identifies the corporate organization, establishes communications protocol, and sets forth the primary job titles, functions, and areas of responsibility.

Facilities and Security – This section sets forth the main operational divisions within the facility, identifying the specific functions of each, and establishes the security requirements of the facility.

Equipment – This section ensures that equipment is properly selected, installed, validated, maintained and disposed of according to established procedures and manufacturer's instructions to meet the needs of the facility and perform quality diagnostic testing.

Purchasing and Inventory – This section ensures an uninterrupted supply of consumables and/or services are available to perform all quality functions. The section mandates that facility maintains a list of vendors that meet the requirements for the product or service to be purchased, that the facility strives to purchase high quality reagents at a reasonable cost and without bias, that the facility has a documented procedure for ordering, receiving, documenting, evaluating and storing all consumables supplies, and that the facility has an inventory management system. The section and governs how the facility selects its referral laboratories and that the facility is responsible for all tests performed by these laboratories.

Process Management – Establishes that the facility has processes for each phase of manufacturing: propagation, vegetation, flowering, and extraction, to ensure a consistent product profile and purity, and that the facility has quality control measures to monitor production.

Assessments – Ensures that the facility strives to continuously improve the quality of facility performance, the effectiveness of the quality management system and the quality of finished product and that the facility does its best to identify and resolve any nonconformity that may affect facility performance and finished product. Establishes that the facility performs ongoing quality assessments such as:

- periodic review of procedure compliance;
- periodic review of procedures with staff and management;
- batch testing;
- participation in internal and external audits.

Personnel - The facility management defines staff educational requirements and competency qualifications necessary for conducting facility procedures. Procedures are established to ensure that the facility management strives to ensure recruitment is unbiased. The facility works with the Human Resources department to ensure education qualifications and references of job applicants are checked and to ensure legal contracts/agreements are signed by all parties prior to employment. The facility has a documented procedure for personnel management.
All personnel (temporary, permanent, students, etc.) sign a confidentiality agreement. All facility personnel respect the facility rules concerning health, safety and security. The facility provides training to its staff according to its needs.

Customer Focus – Facility management is dedicated to providing quality and timely service to all customers, both internal and external. The facility management commits to providing adequate resources to meet customers' requirements and to provide an on-going program for continual improvement.

Non-Conforming Event Management – The facility is committed to the identification, documentation, correction, and prevention of nonconforming events in all aspects of the quality management system including pre-examination, examination and post-examination processes. Procedures are in place that:

- designate the individuals responsible and actions necessary for handling nonconformities;
- ensures that each nonconforming event is documented, recorded, and reviewed at identified intervals, a root cause analysis performed, and that corrective action is taken and documented;
- defines the steps taken when nonconforming product has already been released.

Continual Improvement - A management review is performed annually to evaluate the facility's quality management system, evaluation activities, corrective actions and preventive actions. The facility develops an action plan according to improvement needs every six months and monitors the effectiveness of the actions undertaken.

Documents and Records – The policy provides for the facility to ensure that documents and records are managed from creation and receipt to archival and destruction, according to national laws, local regulations and international standards.

Information Management - The facility has access to the data and information needed to provide a service that meets the needs and requirements of internal and external customers. The facility information system (IS) provides for the collection, processing, recording, storage, and retrieval of data, and has documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process.

C.1.9.4. Audit Programs

During internal audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of plants
- quality control and validation of results
- recording and reporting practices.

External audits will be performed by both third-party ISO consultants to ensure that the quality system in place is adequate and functioning properly, and by government agencies as required.

C.1.9.5. Describe how the results are reviewed to demonstrate the adequacy of the quality system in relation to the objective i.e. quality efficacy and safety of the product.

The findings are compared with the facility's internal policies and to the chosen national or international standard. Any breakdown in the system or departure from procedures should be identified. Any gap or nonconformity in performance shows if the policies and procedures that the facility has set require revision or are not being followed.

C.1.9.6. Record if standards such as ISO 9001-9004 are used by the company to assess its suppliers.

In accordance with ISO 9001, the facility ensures that the procedures for the purchase, receipt and storage of all consumable products and equipment to guarantee that the quality of its extract is not compromised. All new lots are crosschecked and documented with previous lots to ensure

reproducibility. The facility maintains a record of all facility supplies and equipment, including consumables. This information includes:

- identity of the purchased item;
- manufacturers name;
- contact information for the supplier or the manufacturer;
- date of receiving and date of entering into service;
- condition when received (e.g. acceptable or damaged);
- manufacturers' instructions;
- records that confirmed the consumables initial acceptance for use;
- performance records that confirm the consumables ongoing acceptance for use.

C.1.9.7. When suppliers of critical starting materials and packing materials - actives, excipients, containers and closures and printed materials are assessed; give details of how this is done.

The facility evaluates the providers for consumables and equipment. The evaluation should be conducted against defined criteria which may include:

- value for money
- post-delivery support
- availability
- in-country distribution
- registration of the provider.

All the evaluations are recorded and a list of retained providers is established.

C.2. PERSONNEL

C.2.1. Organizational chart showing the arrangements for quality assurance, that includes production and quality control in the case of a manufacturer. In the case of a wholesaler organizational chart showing the arrangements for quality assurance. (see also C.1.9.3).

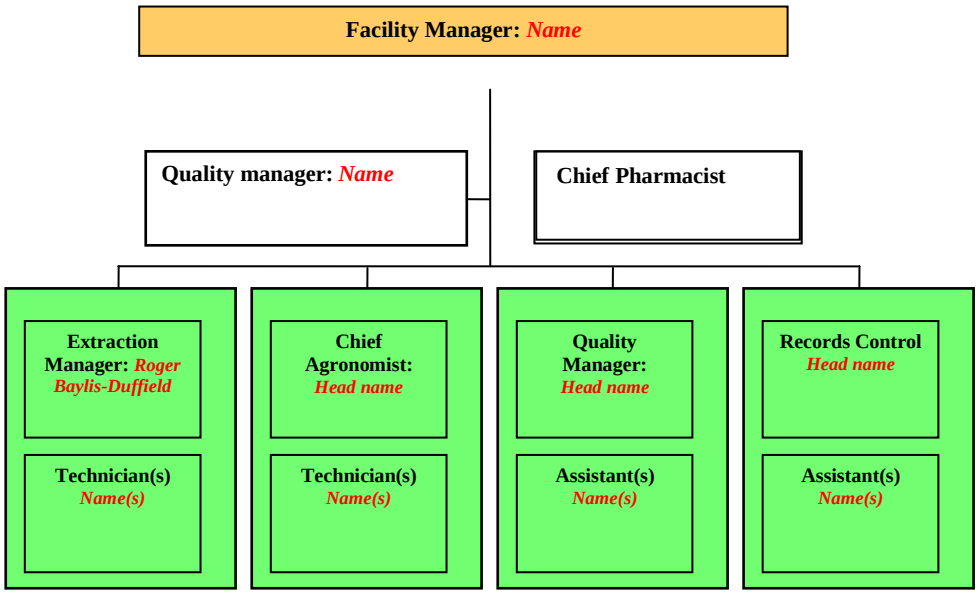
C.2.2. Qualifications, experience and responsibilities of key personnel.

C.2.3. Outline of arrangements for basic and in-service training and how records are maintained.

C.2.4. Health requirements for personnel engaged in production or wholesaling as the case may be.

C.2.5. Personnel hygiene requirements, including clothing.

C.2.1. Organization chart



C.2.2. Qualifications, Experience and Responsibilities of Key Personnel.

Suitable Fit and Proper Requirements: Applicant

> All employees will, prior to their hiring, be subject to a third-party investigation and background check to determine if there are any prior criminal convictions, imposition of civil penalties, revocation of medicine regulation licenses, and the financial situation of individuals, amongst others. These requirements are designed to enable the exclusion of criminal elements, including organized crime, who may otherwise be tempted to use their position for illicit activities.
>
> In addition, employees will undergo an initial drug screening prior to hiring, followed by random drug testing throughout their employment, but no less than quarterly.

Employee files will be maintained that document results of drug screens, training, disciplinary actions and the background check. Additional background checks will be performed on an annual basis.

Facility manager

- designs, approves, implements and maintains the quality management system;
- ensures that the necessary human and material resources, as well as the necessary information, are available to enable effective operation and control of the processes of the quality management system;
- delegates tasks to qualified personnel;
- selects suppliers;
- manages contracts;
- ensures adequate training;
- ensures internal and external communication.

Chief pharmacist

- oversees all aspects of cannabis cultivation and extraction to ensure consistency of quality
- ensures that GMP practices as they relate to pharmaceutical production are followed
- ensures that safety, security, and sanitation standards are in place and followed
- establishes production standards
- reviews and helps implement testing protocols
- reviews and helps implement clinical trials

Quality manager

- assesses the procedures, practices, and training of personnel involved in the facility's activities, in regard to the quality management system;
- reviews the quality plan annually and recommends any revisions needed to the facility's director/manager;
- seeks advice from different departments and specialists and may require assistance from independent experts;
- establishes an internal audit program and informs the facility manager of audit outcomes;
- ensures that the quality management system is managed and maintained;
- establishes and monitors all processes and procedures for the quality management system;
- resolves nonconformities;
- ensures that action is taken in order to obtain continuous improvement of processes/activities;
- ensures all staff has up-to-date QMS training.

Extraction Manager

- plans and co-ordinates the extraction requirements and objectives;
- establishes extraction procedures;
- ensures activities/processes included in the scope of the quality management system are identified and performed in compliance with this manual;
- applies the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective;
- maintains finished product inventory control and security

Chief Agronomist

- plans and co-ordinates the growing activities and objectives;
- establishes growing procedures;
- ensures activities/processes included in the scope of the quality management system are identified and performed in compliance with this manual;
- applies the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective;

- provides training to staff and supervises daily activities

Records Control

- ensures that adequate records are maintained for each department in accordance with the SOP
- safeguards the records against theft or unauthorized access
- prepares reports and notifications to outside vendors, customers and government agencies

C.2.3. Outline of Arrangements for Basic and In-service Training and how Records are maintained Give brief details of the training program and include induction and continuous training, as follows:

Personnel involved in the agriculture side of the business must have a background in botanical/horticultural and undergo specific job function training before starting work. The company will establish a training manual upon the installation of all equipment and maintain training records on all staff. Upon completion of all training modules, employees will be required to take a written test to ensure comprehension and readiness.

Employees will be subjected to periodic retesting, both by observation and written assessment. Employees not meeting the minimum standard, or who are observed violating procedures, will undergo retraining and recertification before returning to active duties. Copies of all tests and observations will be added to employee personnel files.

The Company intends to hire and outside security firm to ensure that such personnel are properly trained and bonded. Any security staff assigned to the company will need to undergo the same background checks and drug screening procedures as full-time employees.

C.2.4. Health Requirements for Personnel Engaged in Production in the case of a manufacturer or picking and packaging in the case of a wholesaler

Employees are to be of general good health, including free from infections and illness. Prior to employment, applicants must complete a blood and urine screen test to ensure they are free from infectious disease and drug use. Test results are maintained in the applicants file.

Employees are routinely and randomly tested for controlled substances, with results becoming part of the employees permanent file. Any violation of the controlled substances policy will result in suspension pending review and appeal of the test results. Confirmed violations will result in termination.

Employees engaged in manufacture, propagation and growing, who are too ill to come to work, or who are sent home due to illness, must be seen by a doctor and receive medical clearance before returning to work.

C.2.5. Personnel Hygiene Requirements Including Clothing

All personnel entrusted with handling herbal material must maintain proper personal hygiene to ensure that the quality of processing, manufacturing and production of Cannabis and Cannabis products are not compromised. Persons suffering from infectious diseases transmittable via food, including diarrhea or carriers of these diseases may not access areas where they could come into contact with herbal material. Persons with open wounds, inflammation and skin infections are not be allowed in areas where they could come into contact with herbal material, unless they wear protective clothing or gloves. All personnel that proceed pass the security check point must wear suitable approved clothing that, at a minimum, incorporates the following:

- Shoes must be covered with disposable booties. Full-time staff may exchange street shoes for appropriate work shoes in the clothing rooms.
- Hair must be covered with approved netting.
- Staff may not wear pants or other clothing that has pockets while in contact with herbal material.
- All personnel admitted past security must don approved outerwear to prevent the introduction or transmission of contaminants.
- All personnel and guests that will have contact with herbal materials shall wear protective gloves and particulate face masks in areas with plant material.
- The Equipment Room will be fitted with rubber gloves and protective eyewear to minimize the risk of exposure to chemicals, including fertilizer.

Supervisors will be responsible for observing employee attire and hygiene and enforcing the company policies.

Soiled clothing, including protective outerwear, will be deposited in marked bins in the changing rooms. The Company will do all laundry in-house to limit the contact with outside contractors.

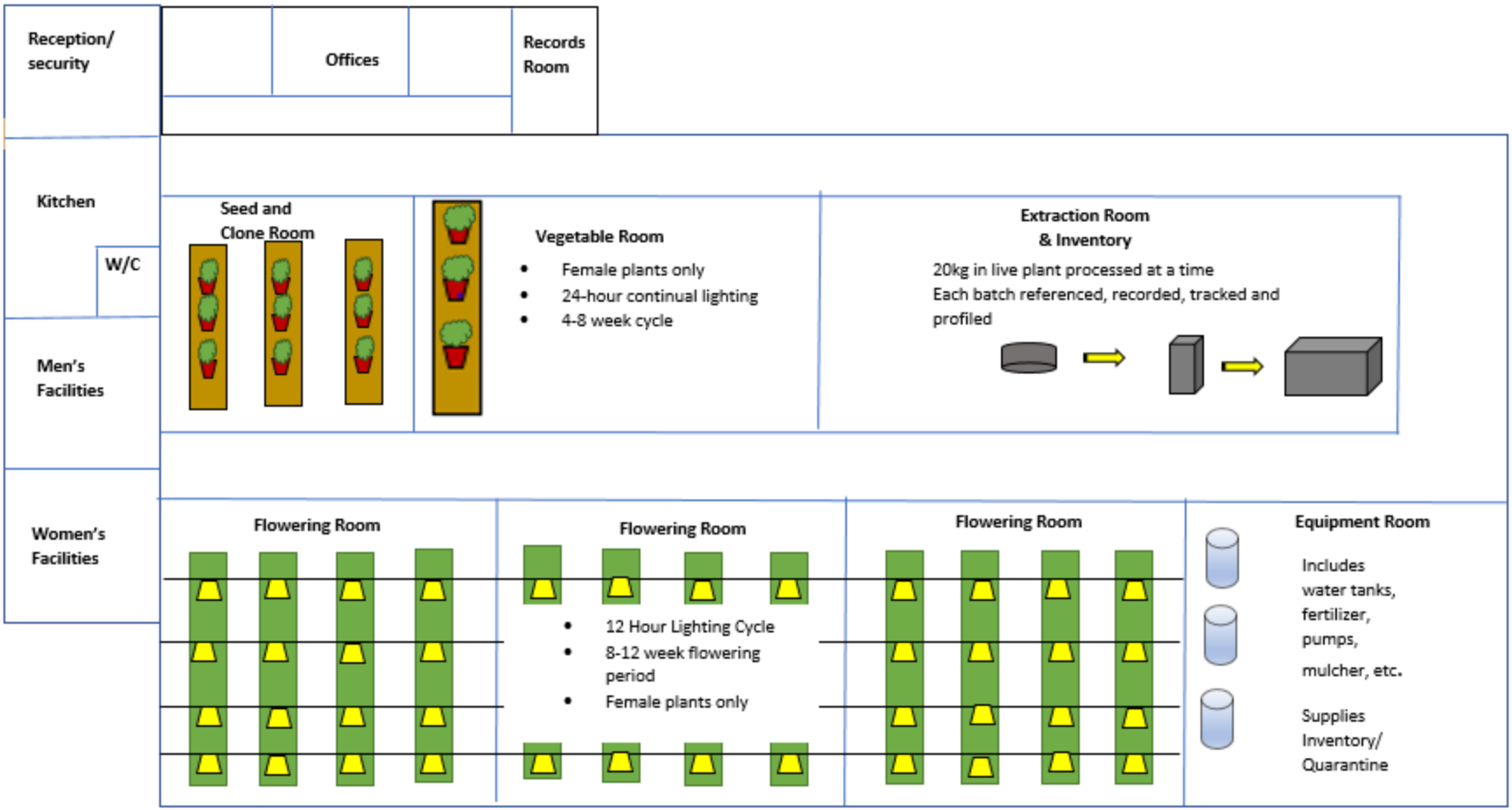
C.3. PREMISES AND EQUIPMENT

Premises

C.3.1. Simple plan or description of manufacturing or wholesaling areas, as the case may be, with indication of scale.

Refer to Facility layout below. Also, attached Exhibits showing building elevation, schematic and aerial photographs.

FACILITY LAYOUT



Scale: 1cm:1m

Reception/Security – This is the only authorized entrance to the facility. All other external doors are locked during business hours, alarmed, and used for emergency exit only. Access beyond this point requires approval from the Company Chief Executive Officer. Approved guests and workers will be required to wear identification badges. Guests will be accompanied by company employees at all times and will be required to sign in and present government- issued identification, which will be photocopied and retained for control purposes. The doors leading from reception to the production area and office are to be locked 24 hours a day using biometric scanning for access.

Records Room – This area is where all production and business records are to be stored, including operating manuals, batch records, shipping documents, plant use and disposal records, personnel files, etc. The door to this area will be locked and accessible only through biometric key pad. File cabinets will be locked and access restricted to authorized personnel.

Men's and Women's Facilities – These separate rooms will be where the production workers don the required clothing to their specific job functions. Clothing worn will have no pockets or other areas for potential concealment, and free from pollen and other outside contaminants. The rooms will be equipped with individual lockers for security and subject to management inspection.

Seed and Clone Room – Pharmaceutical-grade extraction operations necessitate that all plants used share identical chemical properties and that such properties are maintained within set tolerances throughout production. This requirement is met by using a genetically pure seed stock and then cloning the desired plants for all future production. As a final stage, male plants are segregated from the female plants and destroyed (see Equipment Room). Access to this room is through biometric identification to ensure that only authorized personnel are admitted. There will be a plexiglass window in the corridor for monitoring work and observation to minimize access, helping to maintain security and the tight environmental controls. Temperature, light and humidity will be monitored and regulated automatically using the controls in the Equipment room. Plants are watered and fed automatically through installed micro-irrigation systems.

Vegetable Room – Only female plants are brought to this room. Plants are kept here from 4-8 weeks where they are exposed to 24-hour LED lighting. LED lights are the most energy efficient and generate no unwanted heat, which is necessary to maintain stable temperature levels. Temperature, light and humidity will be monitored and regulated automatically using the controls in the Equipment room. Plants are watered and fed automatically through installed micro-irrigation systems. Air flow to this room will be fed through a micro-particulate filter to remove any unwanted contaminants including airborne pollen, spores, dander, etc. Plants are introduced to this room via a pass-through from the Seed and Clone Room. Access to this room is through biometric identification to ensure that only authorized personnel are admitted.

Flowering Rooms – A total of three flowering rooms will be installed, but only two kept in operation, each with 50 plants. This will allow for staggering production so that 50 plants are harvestable, 50 plants maturing, and the empty room being prepared for the next group of plants. This system is preferable to one large room as it prevents possible contaminants, including insect or bacteria, from destroying the entire operation. Plants are kept from 8-12 weeks with alternating 12-hour on, 12-hour off LED lighting. Temperature, light and humidity will be monitored and regulated automatically using the controls in the Equipment room. Plants are watered and fed automatically through installed micro-irrigation systems. Air flow to this room will be fed through a micro-particulate filter to remove any unwanted contaminants

including airborne pollen, spores, dander, etc. Access to this room is through biometric identification to ensure that only authorized personnel are admitted.

Extraction Room – This room will house the necessary extraction equipment to product the finished extract. Equipment includes the cavitation chamber, filters to remove the residual solids, and the powder drying equipment. Finished extract will hermetically sealed in 500g poly bags, batch labeled, and stored in this room. Access to this room is through biometric identification to ensure that only authorized personnel are admitted. Lighting and humidity controls in this room are less stringent, but temperatures need to be maintained to preserve the integrity of the stored extract.

Equipment Room – This room will house the water and fertilization tanks, pumps, and automation equipment in order to minimize human contact. There will be a monitoring station so that humidity, temperature, air flow and lighting can be controlled. This room will also serve as a quality control station where any outside products (soil, fertilizer, supplies etc.) can be inspected and cleared before introduction. A mulcher will be installed to dispose of male plants and residual solids from the extraction process. In accordance with the laws governing plant disposal in South Africa, plant waste is mulched and reintroduced as fertilizer supplement so that no plant material leaves the facility.

C.3.2. Nature of construction and finishes.

Facility is concrete block construction with cement floor and metal roof. Interior walls will fabricated of frame and drywall, finished with anti-microbial paint. Floors will be finished in sheet laminate with edges rolled 4-6" up the wall for cleaning and sanitation purposes. Where appropriate, drop ceilings will be installed with white-room grade acoustic tiles. Non-production areas will have standard acoustic tile drop ceilings.

C.3.3. Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (schematic drawings of the systems are desirable). Classification of the rooms used for manufacture of sterile products should be mentioned.

The entire facility will operate under a closed ventilation system with airflow filtered through a micro-filtration system to prevent contamination. All areas apart from the office area will be positive-pressured as an added protection. Enclosed cultivation operations and processing operations must be equipped with adequate ventilation to maintain proper humidity and temperature. A mechanically propelled air intake system will be used having a filter capable of removing 99.97% of particles with a diameter of 0.3 micrometers (µm), as necessary to control potential contamination with pathogenic organisms.

As part of the Standard Operating Procedure (SOP) for manufacture, the equipment room operator shall monitor all outputs throughout the shift. Specifically, the following are to be noted and recorded every hour:

a. Temperature, humidity and airflow in each flowering room
b. Temperature, humidity and airflow in the vegetation room
c. Temperature, humidity and airflow in the propagation room.

For specific temperature, humidity and airflow requirements by designated area, refer to the Standard Operating Procedures Manual.

C.3.4. Special areas for the handling of highly toxic, hazardous and sensitive materials.

None

C.3.5. Brief description of water systems (schematic drawings of the systems are desirable) including sanitation if applicable.

All water usage will be closed system, meaning that no water from the facility will be returned to the public culinary system apart from water used in restroom facilities, which will be connected to the facility sewer or septic system. Water used in manufacture, propagation and growing areas will be recycled and reused internally.

All water pipes will be of PVC construction with

The Company has not prepared a schematic as plans are pending MCC approval.

C.3.6. Maintenance (description of planned preventive maintenance programs and recording system).

Maintenance shall be done in accordance with the guidelines set forth in the Quality System Manual. At a minimum, all equipment shall be inspected quarterly unless otherwise specified in the operating manuals. Copy of inspection reports shall be filed with the records department.

C.3.7. In the case of a manufacturer, a brief description of major production and control laboratories equipment (a list of equipment is not required).

The management of the facility ensures that equipment is properly selected, installed, validated, maintained and disposed of according to established procedures and manufacturer's instructions to meet the needs of the facility to perform quality diagnostic testing.

New instruments and equipment are installed, calibrated and documented by the vendor who assures satisfactory performance. The facility manager ensures space, ventilation, humidity and electricity meet specifications for satisfactory performance. The vendor provides documentation that each instrument meets all the required criteria for its use in the facility. All equipment is uniquely identified by a unique equipment identifier number. An inventory and master file is maintained for each piece of equipment. The inventory represents the list of all equipment, and persons in charge of the different pieces of equipment. Updating of this inventory is ensured by the persons in charge of the equipment and the facility manager. The same for the attribution of the inventory number of each piece of equipment.

The following information is in the master file:

- name of the equipment
- brand (manufacturer)
- inventory number
- serial number
- model and year
- location
- cost
- date of purchase
- date of first use

- type of maintenance (contract with an external company, in house, etc.)
- regular preventive maintenance to be performed, and frequency to perform these activities
- calibration activities
- record of preventive maintenance activities
- record of repairs
- parts of the equipment that have been changed or repaired.

The following Nexis research greenhouse equipment is to be installed

Cultivation
- Florescent lamps
- Pumps
- Micro-tubing
- Tables – stainless steel
- Biometric scanner
- Temperature gauges
- Humidity gauges

Plandai Processing and Extraction
- Pilot processing system 45 liters 60/40 liquid/solids cannabis flower and leaf
- Storage tank
- Storage tank - Solids removal - analysis
- Storage tank- Oil removal and salt denuding - analysis
- Temperature stabilizing to eliminate degradation issues
- Storage tank - Water removal - analysis
- Vacuum drying into hydroscopic sub-micron particles - analysis

Disposal
- Composter

Other
- Computer systems
- Video cameras
- Alarm system
- Micron air purifying system
- HVAC

C.3.8. In the case of a manufacturer and wholesaler details on maintenance (description of planned preventative maintenance programs and recording system).

Maintenance undertaken in accordance with the guidelines set forth in the Quality System Manual. At a minimum, all equipment shall be inspected quarterly unless otherwise specified in the operating manuals. Copy of inspection reports shall be filed with the records department.

Preventive maintenance is recorded in the instrument daily logbook. Maintenance contracts and warranty service are documented and maintained by the department of service. Copies shall be forwarded to Record Control. Defective or malfunctioning equipment is identified with label alerting

that it is not in use. Equipment requiring service due to a malfunction is decontaminated following manufacturers requirements. Refer to SOP for maintenance and repair procedures and requirements.

Serviced or repaired equipment is calibrated to ensure it meets the manufacturer's performance criteria.

C.3.9. In the case of a manufacturer and wholesaler, details on qualification and calibration, including recording system. Arrangements for computerized systems validation.

To be determined once final equipment is ordered and installed based on manufacturer recommended guidelines.

All equipment certifications and calibration records will be maintained pursuant to the Quality System. The facility validates each new piece of equipment. The validation process depends on the type of equipment and its use in the facility. Reproducibility and accuracy tests are performed, documented, reviewed and approved before the instrument is used in the testing environment.

All equipment used for specific testing is the responsibility of staff in charge of that discipline. The responsible staff conducts or delegates the required calibrations of the equipment and maintains records of all interventions on the equipment.

Use and maintenance of each piece of equipment is based on the manufacturer's instructions. A standard operating procedure (SOP) on the use, maintenance and safety risks of the equipment is accessible at the bench. The operating manual of each piece of the equipment is available in the language spoken and understood by the facility staff.

C.3.10. Availability of written specifications and procedures for cleaning manufacturing or wholesaling areas and equipment.

(a) All employees working in direct contact with cannabis plants shall observe the following general practices:
- No jewelry apart from a wristwatch shall be worn during work hours.
- Employees shall wash their hands with soap and hot water at the beginning of every shift and prior to handling and plants or equipment.
- Employees shall don approved coveralls and rubber boots prior to working in any restricted area.
- Hair nets shall be worn inside of all areas where plant material is present.
- Sterile gloves shall be worn when handling plants.
- Face masks shall be worn inside of all areas where plant material is present.

(b) The Company will provide employees with adequate and readily-accessible toilet facilities.
(1) Toilet facilities must be maintained in a sanitary condition;
(2) Toilet facilities must be adequately stocked with toilet paper, soap, and single use paper towels or other hand-drying devices; and
(3) Toilet facilities must be kept in good repair at all times.

(c) The Company will provide adequate and convenient hand-washing stations.
(1) Hand washing stations must be provided with running water of suitable temperature;
(2) Hand washing stations must be provided with effective hand cleaning or sanitizing preparations and single use paper towels or other hand- drying devices;

(3) Hand washing stations must be located at points in the facility where good sanitary practices require employees to wash or sanitize their hands

Cannabis waste must be composted or disposed of in a manner which prevents unauthorized use and such disposal must be documented. Disposal should not violate any other ordinance, code section or provision of law regarding disposal of cannabis.

Medium, bulbs and ballasts utilized during the cultivation of cannabis must be disposed of in accordance with manufacturer's recommendations, or recycled when feasible.

Nutrients, pesticides, and other chemicals used in cultivation and processing operations must be disposed of in accordance with manufacturer's recommendations.

Disposal Protocol

The following plant material shall be disposed of:

- Unwanted male plants
- Flowering plants after 18 months of production
- Sick or otherwise infected or diseased plants
- Cuttings and trimmings not used in the cloning operations
- Plant solids remaining after extraction

To dispose of plant material, the following shall be noted:

- If a whole plant, the plant identifying number
- The date and time of destruction
- Description of plant matter including approximate weight (ie. – cuttings, extraction solids, etc.)
- Name of individual performing the disposal
- Name of witness to the disposal

After noting the above information, plant material shall be passed through a mulching machine and deposited into the compost receptacle stored in the equipment room. Two people must be involved in the process, one to witness the destruction, and both shall sign the disposal record.

Scissors, razor blades, or other tools for cutting clones shall be cleaned with rubbing alcohol or bleach wipes prior to use. Trays, root zone media and other materials shall be cleaned and wiped with bleach wipes prior to use.

Cloning cubes, cloning powders and gels shall not be reused.

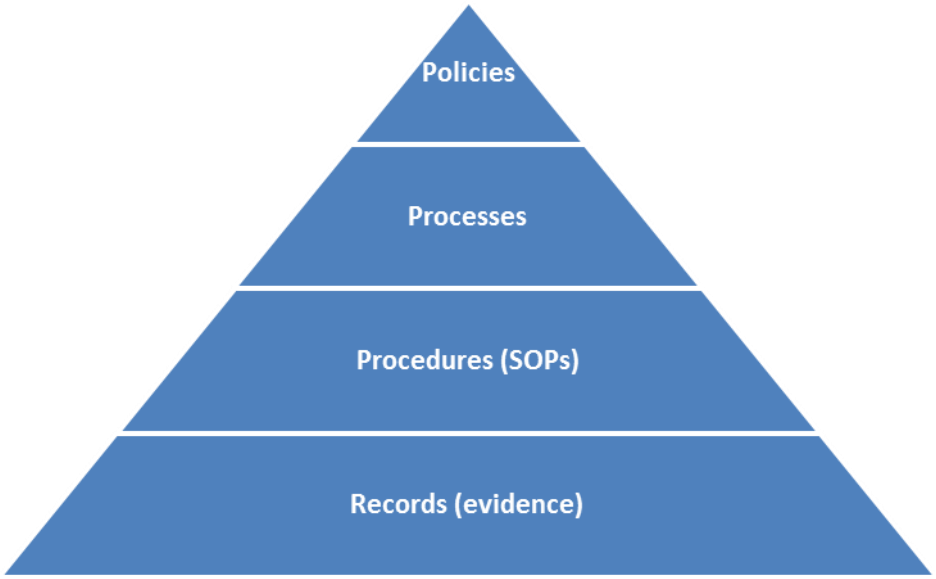
C.4. DOCUMENTATION

C.4.1. Arrangements for the preparation, revision and distribution of necessary documentation for manufacture or wholesale as the case may be.

All document preparation, distribution and storage is outlined in the Quality Assurance manual. The QA manual sets for the required documents and procedures for each function quality area.

The facility ensures that documents and records are managed from creation and receipt to archival and destruction, according to national laws, local regulations and international standards.

The four levels of documentation are represented in the pyramid below.



The quality manager reviews and approves all requests for amendments to existing documents and the development of new procedures, processes, and policies. Staff is not permitted to make temporary amendments to documentation without the prior consent of the quality manager. When new or modified policies, processes and procedures are instituted, staff requires retraining.

The quality manual is reviewed quarterly. All facility procedures are reviewed on an annual basis. The responsibility for the annual review lies with the quality manager. The quality manager is responsible for the distribution of new documents, retrieval of old documents and maintenance of records of amendments.

The company shall have a secure records room that contains both a written and electronic record of all data collected including:

- Production reports
- Variance reports
- Product destruction reports
- Transportation logs
- Security reports
- Personnel files and background checks

All electronic records are to be backed up to a secure drive every 48 hours and stored offsite at a secure location.

The computer and the associated files shall be password protected. All passwords shall be changed every thirty days or in the event of employee termination.

Physical records shall be stored in locked, fire-resistant cabinets.

Access to the records room shall be via biometric code lock to prevent unauthorized access.

(a) The Company will record the identity and source of all cannabis propagation material with sufficient specificity to ensure that the material can be traced to its source. Such records must be created whether the propagation material is obtained off-site or produced on-site.

(b) For each batch of cannabis, The Company will maintain cultivation records that include at a minimum:

(1) Planting records:

(i) Form of cannabis planted (e.g., seed, clone, seedlings, etc.);
(ii) Date(s) that planting took place;
(iii) Variety (ies) planted;

(2) Propagation records:

(i) Media used, and whether the media was reused or new product;
(ii) Description of all actions taken to prevent or treat the cannabis for disease or pest issues;
(iii) Soil amendments added, date of application, and strength of the application;
(iv) Nutrients added, date of application, and strength of the application;
(v) All substances applied to the plant(s) surface or used as a fumigant in the cultivation and/or nursery area and date of application; and
(vi) Pruning or other physical technique(s).

(3)Pesticide use records:

(i) Pesticide chemical name;
(ii) Brand name and manufacturer name;
(iii) Amount of pesticide applied;
(iv) Date pesticide applied;
(v) Cultivation stage at application;
(vi) Identification or location of plants to which pesticide was applied; and
(vii) Name of applicator if required.

(4) Harvest records:

(i) Identity of each variety harvested;
(ii) Date of harvest;
(iii) Gross weight of the cannabis harvested for processing (generally recorded after drying);
(iv) Total weight of cannabis waste resulting from the harvest, and
(v) Net weight of harvested cannabis (gross weight less waste).

(5) Processing Records:

(i) The Company must maintain records for processed cannabis that include at a minimum:
(1) Identity of the variety processed;
(2) Date of processing;
(3) Initial weight; and
(4) Total weight of any processing loss (based on wet or dry weight).

(6) Distribution Records: The Company and processing operations will maintain records of the distribution of the product, including at a minimum:

(i) Total weight distributed;
(ii) Batch number of product distributed;
(iii) Date of distribution;

(iv) Identity of the receiving operation; and

(v) Amount of and the batch or lot number of any variety returned due to product spoilage, recalls, etc.

Record retention

(a) Unless otherwise specified, the Company must retain the records required by this part for a period of three years past date of creation of the record, or one year past the expiration date of the related product, whichever is longer, as applicable to the operation.
(b) Product complaint records must be retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the complaint, whichever is longer.
(c) Records for returned products must be retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the return, whichever is longer.

Information disclosure

(a) The Company must provide relevant records as established herein to regulatory authorities upon request.
(b) Information provided by The Company, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
(c) The Company must disclose the extent and type of testing and analysis conducted on the cannabis it provides, including, but not limited to:

(1) Any tests to determine the quantitative levels of contained constituents, such as individual cannabinoids and terpenes, and if so, the type of testing used;

(2) Any tests to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. The information required by this paragraph must be disclosed for each of the following:
(i) Common or known pesticides;
(ii) Yeasts and molds;
(iii) Other microbiological contaminants; and
(iv) Heavy metals.

(3) Whether the testing was conducted by The Company, or by an external laboratory.

All documents are uniquely identified. Date of issue, revision version, total number of pages and authorizing signatories are included in the document.

Documents are signed as a paper copy or authorized electronically.

A document control log is maintained identifying the current valid versions and their distribution.

A secure master file is maintained of all documents to prevent unauthorized access, loss or damage.

Records Control is responsible for the proper archiving of documents and records. This activity is coordinated with the Quality Manager.

The facility respects the national regulations or legislations concerning the retention time of all records.

A copy of an obsolete document is kept indefinitely to provide a means for review if the situation arises.

C.5. PRODUCTION OR WHOLESALING

C.5.1. Brief description of production operations or wholesaling activities as the case may be using, wherever possible, flow sheets and charts specifying important parameters (see at Appendix the list of products manufactured or wholesaled).

The Company will engage in the propagation, cultivation and recovery of cannabis phytonutrients, which will be delivered into a sub nano powder, 3% moisture and stored in hydrogen for medical testing. No sales activities, wholesaling or distribution activities are planned for this facility. Finished product will be shipped from the facility to laboratories for analytical testing and to qualified research institutions for scientific and medical investigation.

Standard operating procedures are in place for all production and manufacturing activities in accordance to GMP practices. SOPs, and any changes thereto, will be submitted to the MCC for review. SOPs are dependent on specific equipment installed and will include the following parameters, each of which will be standardized to ensure consistency of finished product:

- Order of daily tasks
- Plant tracking
- Equipment usage
- Watering schedule
- Water and fertilization system operation
- Waste water disposal
- Lighting schedule
- Cultivation procedures
- Harvesting procedures
- Extraction procedures
- Waste disposal procedures
- Packaging
- Pest control and mitigation
- Environmental controls and settings, including humidity, airflow and temperatures

Processing

Only live plant (flower and leaf) will be used in the extraction process, thus there will be no concern with drying, storing, or packing of plant material. Finished extract will be in a hygroscopic powder form and protected in nitrogen.

Packaging of finished extract will be no larger than 500g (1/2 kg) Mylar bags. Each bag will be filled with hydrogen and immediately vacuum sealed to ensure that the chemical profile is not compromised. Bags will be labeled by batch to record date of manufacture.

Solids removed in the extraction process will be analyzed before composting or formulating as an ingredient into other commercial applications such as briquettes

Used water from the extraction process will be analyzed, filtered and recycled into the production process such that the entire system will be self-contained.

Quality and Safety

Analytical investigations and product profiling will be undertaken by Labserve Analytical Services, Nebo Park, Suikerriet Street, Nelspruit 1200 on every batch of extract produced and prior to release from Quarantine:

- Appearance
- Foreign Material
- Fineness
- Identification A: Microscopic Properties
- Identification B: TLC
- Microbiological Contamination
- Aflatoxins
- Pesticides
- Heavy Metals
- Assay and Related Substances
- Chemical profile

Storage

Finished product will be stored in Mylar hydrogen bags on rack shelving in the Extraction Room. This room is secured and accessible only by biometric scan. The room is both climate and temperature controlled.

C.5.2. Arrangements for the handling of starting materials. packaging materials, bulk and finished products, including sampling quarantine, release and storage applicable to manufacturing or wholesaling as the case may be.

Purchasing orders

The orders for purchase of supplies (consumables and materials) are requested using a specific form and submitted to the provision/purchasing department.

Receipt of orders

The facility confirms receipt of the supplies with the assistance of the financial department/ provision department.
The date of receipt is recorded. The person in the facility taking receipt of the supplies crosschecks the information indicated on the package and accompanying documents with the data of the order.

Materials are transferred to a designated Quarantine area until items can be inspected and cleared for use. Once Cleared, the items are entered into Inventory and moved out of Quarantine.

The facility has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates. A regular inventory is performed.

C.5.3. Arrangements for reprocessing or rework.

Given the nature of the extraction process, it will not be possible to reprocess or rework defective or non-conforming product. All non-conforming product will be labeled and recorded to ensure proper traceability, and then destroyed.

C.5.4. Arrangements for the handling of rejected materials and products.

Cannabis waste must be composted or disposed of in a manner which prevents unauthorized use and such disposal must be documented. Disposal should not violate any other ordinance, code section or provision of law regarding disposal of cannabis.

Medium, bulbs and ballasts utilized during the cultivation of cannabis must be disposed of in accordance with manufacturer's recommendations, or recycled when feasible.

Nutrients, pesticides, and other chemicals used in cultivation and processing operations must be disposed of in accordance with manufacturer's recommendations.

Disposal Protocol

The following plant material shall be disposed of:

- Unwanted male plants
- Flowering plants after 18 months of production
- Sick or otherwise infected or diseased plants
- Cuttings and trimmings not used in the cloning operations
- Plant solids remaining after extraction

To dispose of plant material, the following shall be noted:

- If a whole plant, the plant identifying number
- The date and time of destruction
- Description of plant matter including approximate weight (ie. – cuttings, extraction solids, etc.)
- Name of individual performing the disposal
- Name of witness to the disposal

After noting the above information, plant material shall be passed through a mulching machine and deposited into the compost receptacle stored in the equipment room. Two staff members will be involved in the process, one to witness the destruction, and both shall sign the disposal record.

During the extraction process, unused plant material shall be disposed of using the Disposal Protocol. Residual plant solids that remain following the extraction and filtration process shall be collected and disposed of using the Disposal Protocol.

Finished product that is deemed unusable will be clearly labeled, documented, then disposed of using the Disposal Protocol.

C.5.5. In the case of a manufacturer a brief description of the general policy for process validation.

Only plant material meeting specifications and requirements may be released for the next phase of processing. An indication of approval should be placed on the cannabis. Cannabis not meeting specifications and requirements may not be released to the next phase of processing. An indication of rejection should be placed on the cannabis and the Disposal Protocol followed.

Process validation on finished product is performed in two parts. Part 1 is a visual and physical inspection performed by the Extraction Engineer, who examines the product for color, smell, micron size, contamination and failure to properly render into powder. Further validation is performed by third parties. The following analytical tests will be performed by Labserve Analytical Services, Nebo Park, Suikerriet Street, Nelspruit 1200 on every batch of extract produced and prior to release from Quarantine:

- Appearance
- Foreign Material
- Fineness
- Identification A: Microscopic Properties
- Identification B: TLC
- Microbiological Contamination
- Aflatoxins
- Pesticides
- Heavy Metals
- Assay and Related Substances
- Chemical profile

A detailed report is prepared and attached to each batch before it can be cleared and moved from Quarantine into Finished Goods Inventory. As these are the only measurable factors in the chain, process validation is indicated by the positive test results.

The validation process for equipment depends on the type of equipment and its use in the facility. Reproducibility and accuracy tests are performed, documented, reviewed and approved before the instrument is used in the testing environment. All equipment used for specific testing is the responsibility of staff in charge of that discipline. A standard operating procedure (SOP) on the use, maintenance and safety risks of the equipment is accessible at the bench. The operating manual of each piece of the equipment is available in the language spoken and understood by the facility staff.

C.6. QUALITY CONTROL

C.6.1. Description of the Quality Control system and of the activities of the Quality Control Department Procedures for the release of finished products.

The Quality Control system dictates that all finished product is moved to Quarantine pending testing and release. The following analytical tests will be performed by Labserve Analytical Services, Nebo Park, Suikerriet Street, Nelspruit 1200 on every batch of extract produced and prior to release from Quarantine:

- Appearance
- Foreign Material

- Fineness
- Identification A: Microscopic Properties
- Identification B: TLC
- Microbiological Contamination
- Aflatoxins
- Pesticides
- Heavy Metals
- Assay and Related Substances
- Chemical profile

A detailed report is prepared and attached to each batch before it can be cleared and moved from Quarantine into Finished Goods Inventory.

Product shall be released from the facility only upon the written instruction of the Chief Executive Office using the Product Release Form. The form shall include the following:

a. Quantity of product being shipped
b. Date of shipment and estimated delivery date
c. Method of shipment
d. Identity, address and telephone number of recipient
e. Any other transportation instructions required
f. Intended use of the product (research purpose, etc.)

C.7. CONTRACT MANUFACTURE AND ANALYSIS

C.7.1. Description of the way in which the GMP compliance of the contract acceptor is assessed.

The facility evaluates the providers for contractors and third party analytics. The evaluation should be conducted against defined criteria which may include:

- value for money
- post-delivery support
- availability
- in-country distribution
- registration of the provider.

All the evaluations are recorded and a list of retained providers is established.

C.8. DISTRIBUTION, COMPLAINTS AND PRODUCT RECALL

C.8.1. Arrangements and recording system for distribution.

All finished product is stored in the extraction room, which is both climate and temperature controlled. The room is secured by biometric identification and only accessible to authorized personnel. Product shall be released from the facility only upon the written instruction of the Chief Executive Office using the Product Release Form. The form shall include the following:

a. Quantity of product being shipped
b. Date of shipment and estimated delivery date

c. Method of shipment
d. Lot number
e. Identity, address and telephone number of recipient
f. Any other transportation instructions required
g. Intended use of the product (research purpose, etc.)

Only Phytofare® extract and purified cannabinoid oil will be removed from the facility. While neither product will have psychoactive properties, care must still be taken to prevent theft, loss or damage to the product.

Shipments inside of South Africa –

h. Shipments to locations within South Africa are to be made by vehicular transport only.
i. The vehicle used shall be fitted with a secure vault or safe to be located in a locked trunk.
j. The driver shall pick up the delivery from Security and note the time of receipt and estimated time of delivery.
k. Driver shall sign the log indicating receipt of the product, noting quantity received.
l. The vehicle shall have a full tank of petrol prior to pick up.
m. Driver shall have a working cell phone and contact security in the event of any vehicle or other problems.
n. Security shall remain on alert and be available to render assistance in the event of a vehicle emergency.
o. At delivery, driver shall obtain the signature of the recipient and pertinent recipient information including name, address, time and date of delivery. Driver shall verify this information by inspecting government-issued identification.
p. Recipient shall note and initial the quantity received on the transportation paperwork.

Shipments outside of South Africa –

q. Shipments must have proper exportation and importation documentation.
r. Product is to be placed in an unmarked box and sealed with packing tape.
s. Recipient name and address are to be noted on the box and in the records.
t. The following information is to be noted in the records:
    - Date of shipment
    - Courier name
    - Estimated time of delivery
    - Quantity shipped
    - Lot number
    - Name and address of recipient
u. Only a qualified and bonded courier company may be used (DHL or other similar).
v. If the parcel is to delivered to the courier, the same protocol for delivery of product inside of South Africa is to be followed until the product arrives at the courier.
w. Company shall verify in writing from the recipient that product has been received noting date of receipt, condition of package, and quantity received.

Variances between quantity of product that ships and quantity received are to noted and the MCC and law enforcement notified immediately.

C.8.2. Arrangements for the handling of complaints and product recalls.

Complaints

Product complaints shall be noted on the Product Complaint form. The following shall be noted:

(1) Date of complaint
(2) Name of complainant
(3) Nature of complaint
(4) Batch number of product subject to complaint

Complaint form shall be reviewed by Quality Manager and Facilities Manager to determine appropriate course of corrective action. Complaint shall be stored for five years.

Facilities Manager shall follow up with customer to advise of corrective action, if needed.

Corrective action taken shall be noted in Corrective Action form and incorporated into all subsequent SOP versions. Staff shall be retrained as necessary.

Product Recalls

Prior to introducing the product to market, the Company will develop and implement a recall plan addressing at a minimum:

(1) Factors which necessitate a recall procedure;
(2) Personnel responsible for a recall; and
(3) Notification protocols.

The Company policy for communicating a recall will include:

(1) A mechanism to contact all customers who have, or could have, obtained the cannabis from the cultivation operation or processing operation, which communication must include information on the policy for return or proper disposal of the recalled product; and
(2) Communication and outreach via media, as necessary and appropriate.

Any recalled product that is returned to The Company must be disposed of in a manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person.

C.9. SELF INSPECTION

C.9.1. Short description of the self-inspection system See also para 1.9.4.).

During internal audits, information is gathered about:

- processes and operating procedures
- staff competence and training
- equipment
- environment
- handling of plants
- quality control and validation of results
- recording and reporting practices.

The findings are compared with the facility's internal policies and to the chosen national or international standard. Any breakdown in the system or departure from procedures should be identified.

Any gap or nonconformity in performance shows if the policies and procedures that the facility has set require revision or are not being followed.

All corrective actions undertaken in the facility will be reviewed and their follow up evaluated. Refer to Chapter 11 - Nonconforming Event Management in the Quality System Manual.

Quality indicators have been determined for six months to monitor the quality objectives of the facility. This monitoring is detailed in Chapter 12 - Continual Improvement of the Quality Systems Manual.

All staff is encouraged to offer suggestions for improvement of any aspect of the facility. These suggestions are recorded, evaluated and implemented if useful. Feedback on the suggestions implemented is provided to the staff.
Requests are systematically reviewed to evaluate the appropriateness of the methods used for production.

All procedures are also reviewed every three months to ensure that the latest industry advances in production have been considered and to determine if existing procedures are both effective and efficient.

C. 10. SECURITY

Security provisions

(a) The facility shall employ 24-hour, independent security.
(b) All security personnel shall be required to complete full background checks and a drug screen before being assigned to the company. The company will obtain the results of these screenings.
(c) All personnel working inside the facility will be required to complete full background checks and a drug screen before commencing work. The company will obtain the results of these screenings and store them in the personnel files.
(d) All personnel and security shall be subjected to random and periodic drug screening at least once per quarter. Testing positive for cannabis or any other illegal drug shall be cause for immediate dismissal and the results shall be forwarded to the MCC.
(e) Video cameras shall be installed in all rooms of the facility and outside the building covering all potential access points. Video recordings shall be retained as follows:
    a. External footage – 7 days
    b. Records room – 7 days
    c. Propagation and vegetation rooms – 14 days
    d. Flowering rooms – 30 days
    e. Equipment room – 7 days
    f. Extraction room – 7 days
(f) In the event of lost or stolen plant material, all video records shall be immediately archived in the records room pending notification of law enforcement personnel and the MCC.
(g) All visitors shall be required to check in at the security/reception area. Visitors shall provide identification and security shall note the following:

a. Visitor name and permanent address
b. Date of time of arrival
c. Purpose of visit
d. Name of escort
e. Time of departure

(h) Visitors shall not be permitted to take cell phones, cameras, or personal effects, including purses or briefcases, in to the production areas.

(i) The facility shall be equipped with an alarm system to notify of any unauthorized access.
    a. Internal doors, apart from the main security entrance, are to be locked from the inside at all times, with alarmed access only in the event of emergency.

(j) Outside of business hours, the facility shall have two guards stationed outside the building at all times.

(k) Employees shall be subject the physical search at any time. All personal effects shall be inspected upon leaving the facility.

(l) Any breach of security shall be notified to law enforcement immediately. The MCC shall be advised of all security breaches.

6 APPENDIX

TYPE OF PRODUCTS MANUFACTURED OR WHOLESALED (referred to in paragraph C.1.5)

A. Sterile products

None

B. Non-sterile products

B.1 Liquid dosage forms

The facility will produce a cannabis oil byproduct.

B.5 Multi dose form (powder, granules)

The facility will produce a cannabis extract complex rendered into a powder form.

C. Biological products

None

D. Specifically toxic and hazardous substances

None

E. Primary and or Secondary Packaging only

Cannabis extract will be stored in 2kg foil bags, nitrogen flushed and heat sealed. All bags will be labeled with batch number, and date of manufacture. Cannabis oil will be stored in sealed plastic containers and labeled with batch number and date of manufacture.

F. Contract manufacturing (kind of products)

None

G. Contract analysis

Firm reported upon is:

F.1. Contract Acceptor
F.2. Contract Giver

H. Drugs for clinical trials

None

I. Others

None

7 EXHIBITS

7.1 Architectural Plan – Ground Floor

7.2 Architectural Site Plan

7.3 Aerial Photo of Facility

7.4 Aerial Photo of Facility and Surrounding Environs

7.5 Letter from Coega to Plandaí Biotechnology