Medicines Control Authority of Zimbabwe

CANNABIS LABORATORY

MCAZ Cannabis Laboratory - Services Offered

The Medicines Control Authority of Zimbabwe (MCAZ) is a regulatory body established by the Medicines and Allied Substances Control Act (MASCA) [Chapter 15:03] and its Regulations, S.I 150 of 1991. The Authority`s mandate is set out in this Act and its accompanying regulations. It is also responsible for administering the Dangerous Drugs Act (Chapter 15:02) and its regulations, Dangerous Drugs Regulations (RGN 1111 of 1975) on behalf of the Ministry of Health and Child Care.

The Dangerous Drugs Act [Chapter 15:02] is an Act that provides for the control of the importation, exportation, production, possession, sale, distribution and use of dangerous drugs; and to provide for matters incidental thereto. In terms of Section 6 of the Dangerous Drugs Act [Chapter 15:02], the Minister of Health and Child Care published the Dangerous Drugs (Production of Cannabis for Medicinal and Scientific Use) Regulations, 2018, Statutory Instrument 62 of 2018, hereinafter referred to as “Regulations”.

The role of the Regulator hence is to ensure that cannabis, cannabis-based products and hemp are safe, of high quality, consistent and meet customer satisfaction. This brochure highlights some of the key tests done by the Cannabis Laboratory at MCAZ. The laboratory carries out tests in accordance with International Standards and Pharmacopoeia such as BP, USP, European Pharmacopoeia, and WHO guidelines

POTENCY TESTING

The MCAZ Cannabis lab is mandated to test and determine the Total THC content of all cannabis and cannabis related samples meant for use and export. The difference between medicinal cannabis and industrial hemp is the content of their psychoactive component delta-9 tetrahydrocannabinol (Δ^9THC).According to the Criminal Law (Codification and Reform) Amendment Act 2023 section 155 of Cap. 9:23 “industrial hemp means the plant cannabis sativa L and any part of that plant, including the seed thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts and salts of isomers, whether growing or not with a delta-9-tetrahydrocannabinol concentration of not more than one per centum (1%) on a dry weight basis.

Figure 1: MCAZ’s dedicated Potency Analyser

EQUIPMENT

The MCAZ Cannabis laboratory is equipped with state-of-the-art equipment including the Potency Analyser which is designed specifically for cannabis potency analysis. This turnkey HPLC shown in **Figure 1** has become the gold standard for cannabinoids profiling.

Service Delivery Time.

The MCAZ Cannabis laboratory commits to a turnaround time of ten (10) working days for sample received for potency analysis. The laboratory ensures that certificates of analysis are produced in the shortest time possible

Recommended Sample Size for Potency Test

The quantities of samples to be submitted by clients for potency testing are illustrated in Table 1

Table 1: Guidance on sample sizes to be submitted for potency testing.

Test	Minimum Quantity of Flower Required	Minimum Amount of Oil Required
Cannabinoid potency (measure concentration of THC/THCA, CBD/CBDA)	20g	10ml
Cannabinoid Profiling	20g	10ml

RESIDIUAL SOLVENTS AND TERPENES

Residual solvents are solvents left over from the process of extracting cannabinoids from the cannabis plant. Most cannabis concentrates are extracted using a solvent such as supercritical CO2, butane, hexane, propane, and other alcohols. These solvents are used to extract out the cannabinoids and terpenes from the plant material. In some cases, impurities from the solvent remain in the final cannabis product. These are called residual solvents and understanding their concentration is a critical element of cannabis testing.

Figure 2: State of the art GC-MS for residual solvents and terpenes testing

EQUIPMENT

The testing for residual solvents requires gas chromatography (GC) with headspace. This method of choice for a simple technique allows only the volatile component of the cannabis sample to be measured. The MCAZ Cannabis Laboratory is equipped with a gas chromatography coupled with a mass spectrometer GC/MS-HS which can analyse both residual solvents and terpenes. With this technique, we can isolate, identify and analyse different types of terpenes.

Service Delivery Time.

The MCAZ Cannabis laboratory commits to a turnaround time of ten (10) working days for samples received for residual solvents and terpenes analysis. The laboratory ensures that results and Certificates of analysis are produced in the shortest time possible

Recommended Sample Size for Residual Solvents and Terpenes

The quantities of samples to be submitted by clients for testing residual solvents and terpenes in cannabis samples are illustrated in Table 2

Table 2: Guidance on sample quantities to be submitted for residual solvents and terpenes testing.

Test	Minimum Quantities of Flower Required	Minium Amount of Oil Required
Residual Solvents	Not applicable	5ml
Terpenes Profile	10g	10ml

PESTICIDES RESIDUES

A pesticide is any substance or mixture of substances intended for preventing, destroying or controlling any pest, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of herbal drugs. These substances are intended for use as growth-regulators, defoliants or desiccants. They are applied to crops, either before or after harvest, to protect the commodity from deterioration during storage and transport. Pesticide residues can be present and are controlled in herbal drugs and herbal drug preparations.

Figure 3: The advanced LC-MS for pesticides testing

EQUIPMENT

The MCAZ Cannabis Laboratory is equipped with a LCMS/MS-8050 instrument. This system has ultra-low detection limits, high sensitivity and excellent throughout suitable for analysing most pesticides used in the cannabis industry. Liquid chromatography-tandem mass spectrometry (LC/MS/MS) has become the method of choice for pesticide analysis due to its high selectivity and sensitivity as well as its suitability for a wide range of compounds in different sample matrices

Service Delivery Time.

The MCAZ Cannabis laboratory commits to a turnaround time of ten (10) working days for sample received for pesticides residues analysis. The laboratory makes efforts to o ensure that results and Certificates of analysis are produced in the shortest time possible

Recommended Sample Size for Pesticides Testing

Below is a guidance on sample size requirements for analysis of pesticides residues in cannabis.

Table 3: Guidance on sample quantities to be submit by clients for pesticides testing

Test	Minimum Amount Flower Required	Minimum Amount of Oil Required
Analysis of Pesticides Residues in Cannabis	10g	Not applicable

HEAVY METAL TESTING

Certain heavy metals are toxicants that cause adverse effects on human health. Toxic heavy metals such as arsenic, cadmium, lead, and mercury are persistent once released into the environment and can accumulate in Cannabis plants. Cannabis-based products such as edibles, oils, tinctures and salves must, therefore, be tested for the presence of heavy metals to ensure patient safety and product quality. Harmful toxic elements can be absorbed into cannabis plants primarily through uptake from soil, water, and fertilizer. Concentrations are at comparatively trace levels – in the parts per billion or parts per trillion – but can still be harmful to end consumers. As such, it's important to measure the toxic elemental content of plants and plant materials

Figure 4: A modern ICP-MS for heavy metals testing

EQUIPMENT

For testing of heavy metals, the Cannabis Laboratory has the latest ICPMS instrument. This instrument can analyse up to 96 samples in a single day making it the fastest and only reliable heavy metal analysing instrument in the country. Our ICPMS-2030fF can provide reliable and accurate results within minutes.

Service Delivery Time.

The MCAZ Cannabis laboratory commits to a turnaround time of five (5) working days for sample received for Heavy Metal testing. However, the laboratory ensures that results and Certificates of analysis are produced in the shortest time possible

Recommended Sample Size for Pesticides Testing

Below is a guidance on sample size requirements for heavy metal testing in cannabis.

Table 4: Guidance on sample quantities to be submitted by clients for heavy metals testing

Test	Minimum Amount Flower Required	Minimum Amount of Oil Required
Analysis of Heavy Metal Testing	20g	5ml

MOISTURE CONTENT

Moisture content can be extremely detrimental to the quality of stored cannabis products. High moisture content in cannabis can lead to a variety of issues, including mold and bacteria growth, reduced shelf life, and loss of potency. On the other hand, too little moisture can cause a plant to become brittle and less desirable. In general, cannabis products should have a moisture content between 10 and 15 percent to prevent mold growth and ensure proper preservation. It is important to maintain the moisture content and water activity in cannabis products to prevent degradation and thereby safeguarding the product's quality.

Figure 5: Instrument for moisture content determination

EQUIPMENT

Our moisture analyser uses thermogravimetric method which involves placing a cannabis sample into the sample chamber and heating it until all moisture has evaporated out of the sample. This method is so accurate as it gives the percentage weight of moisture that was contained in the original sample.

Service Delivery Time.

The MCAZ Cannabis laboratory commits to a turnaround time of three (3) working days for sample received for moisture content determination. The laboratory ensures that results and Certificates of analysis are produced in the shortest time possible.

Recommended Sample Size for Pesticides Testing

Below is a guidance on sample size requirements for analysis of pesticides residues in cannabis.

Table 5:Guidance on sample quantities to be submitted by clients for moisture content testing

Test	Minimum Amount Flower Required	Minimum Amount of Oil Required
Loss on Drying (LoD)	10g	Not applicable
Moisture Content	10g	Not applicable

PRECISION WEIGHING

Figure 6: One of analytical balances for weighing

Reliable, reproducible weighing results are critical in sample analysis. Our top of the range analytical balances are calibrated and certified by the National Metrology Institute of the Scientific and Industrial Research and Development Centre (SIRDC-NMI).

MICROBIAL TESTING

The presence of dangerous pathogens, such as *Aspergillus spp*. and *E. coli*, in cannabis products can pose a threat to consumers. Early microbial detection is essential to avoid reaching fatal levels of contamination in cannabis and hemp plants

The MCAZ's Microbiology Laboratory is responsible for microbiological quality control testing of medicinal products including cannabis and cannabis related products. The laboratory was recently upgraded to a state-of-the-art laboratory to meet WHO Prequalification (PQ) requirements for Pharmaceutical Microbiology Laboratories. It is now also an ISO17025 accredited laboratory.

TRAININGS

LABORATORY TRAININGS

The laboratory also offers trainings on laboratory operations and systems to interested customers. Training is conducted at a fee and could be in the form of attachments, short courses, and exchange programs.

TRAININGS OFFERED

The trainings cover but not limited to the following areas:

- Hands on Advanced Analytical Equipment training on the GCMS, ICPMS, HPLC and LCMS.
- Cannabis and Complementary Medicine samples analysis

TRAINING ARRANGEMENTS

These trainings can be tailor-made to suit the client’s requirements.