



POTENCY

Cannabinoid profiling informs patients about the concentrations of active cannabinoids in their medicine. Researchers have identified over 130 cannabinoid compounds, many of which possess distinct medicinal benefits. An assay to establish the concentration of the active ingredients in a medicinal product is a requirement by SAHPRA (South African Health Products Regulatory Authority) according to cGMP (Current Good Manufacturing Practice). Potency should be tested on all medical cannabis products or derivatives thereof. As is the case with any pharmaceutical product, the active ingredients in cannabis should be clearly labelled with a concentration associated to each. Cannabinoid profiling allows doctors to determine accurate dosage, ensures that providers can verify the quality of their products, and helps patients to select the right treatment for their symptoms.

As a result of the natural origin of medicinal cannabis products, the concentration of cannabinoids in the plants themselves may vary significantly depending on growth conditions such as: temperature, humidity, nutrients, region, strain, sunlight etc. These plant extracts or oils may inherently also differ in cannabinoid concentration as a result of these conditions. It is thus imperative that the concentration of each batch of medicinal cannabis produced be tested for potency (Cannabinoid concentration) to ensure accurate consistent dosing and batch to batch repeatability. The World Health Organization suggests sampling of herbal medicine batches for testing should contain $(1.5 \times \sqrt{n})$ samples, where n is the number of individual packaged units.

AOAC International has published draft methods for the standardization of medicinal cannabis potency testing. We at NAFS employ two independent lots of internationally obtained certified cannabinoid reference standards (CRM's). These CRM's are employed for calibration and comparison purposes. The range of potency analytes we currently test for include a total of 10 different major cannabinoids, including a decarboxylation calculation for Total Potential THC and CBD.

POTENCY %WEIGHT VS. MG/ML

Usually potency is reported as a %weight of the sample, especially for raw plant materials, since an accurate volume can not be determined. For example, a gram of raw plant material contains a certain %weight of cannabinoids. Thus, if the %weight for THC is 5 %weight, it means that any weighed portion in grams of the sample should contain 5% THC in grams. If 10 grams of sample is weighed 5 %weight would translate to 0.5 g of THC. The following formula can be used to back calculate the grams of a cannabinoid from the %weight measurement:

$$\%weight \div 100 \times Sample\ Weight(g) = Cannabinoid\ Weight(g)$$

To obtain a different unit such as mg/mL compared to %weight, the %weight of the sample as well as the density needs to be known. The density of a sample describes the weight of a sample that occupies a set volume. The weight of 1 mL of water is approximately 1 g at standard temperature and pressure.



%WEIGHT VS. MG/ML (CONTINUED)

If this approximation is applied to other viscous sample types the mg/mL calculation will be inaccurate, hence a density measurement is needed to accurately quantitate the amount of cannabinoids per volume unit of the sample. To translate %weight to mg/mL a certain volume of liquid sample needs to be weighed in order to determine the sample density. From this density the mg/mL of cannabinoids can be calculated using the %weight unit. NAFS offers Potency mg/mL content as a test panel where % weight as well as density is determined. It should be noted that only liquid samples can be submitted for this test. Crude extract oils and other highly viscous samples can not be accurately pipetted and subsequently can not be submitted for Potency mg/mL.

ISOLATE PURITY ASSAY

Purified single cannabinoids are referred to as isolates. These isolated cannabinoids are extremely concentrated and difficult to analyse using conventional calibration curves. At NAFS we employ a dual verification method using two different instrumental techniques: Fourier Transform Infrared Spectroscopy (FTIR) and Ultra High Performance Liquid Chromatography - Ultraviolet-Visible spectroscopy (UPLC-UV-Vis). When employing FTIR analysis a CRM library is used to match the unknown isolate sample against, confirming the isolates' identity. Subsequently a UPLC run, combining the total UV spectrum wavelength of 200nm to 500nm, is used to report a %area of the main component together with the %area of the impurities found.

TEST PANELS

Potency (%weight)

-CBC	-CBN
-CBD	-THC
-CBDA	-THCA
-CBDV	-THCV
-CBG	-Total Potential THC
-CBGA	-Total Potential CBD

Potency (mg/mL)

-CBC	-CBN
-CBD	-THC
-CBDA	-THCA
-CBDV	-THCV
-CBG	-Total Potential THC
-CBGA	-Total Potential CBD

Isolate Purity Assay

-FTIR Identification
-UPLC-UV-Vis %Purity

PRICING

Potency	-See Pricelist
Bulk samples	-Discounted

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