PROPOSED STANDARDS FOR CANNABIS AND CANNABIS PRODUCTS

1 Rationale

1.1 Currently, there are no standards for cannabis or for products containing cannabis or cannabinoids in South Africa.

1.2 A tested and certified product should be the norm – growers, producers and consumers need to have accurate information about the product they are growing, manufacturing or consuming.

1.3 An environment of testing and certification will enhance the reputation of producers, importers, suppliers of products, etc.

1.4 As an industry leader in cannabis testing in South Africa and part of the SABS technical committee to develop standards for cannabis, Qure is proposing the set of standards outlined below. These standards will give customers and consumers an indication of the quality of their products.

1.5 Qure's proposed standards are based on current international standards for cannabis; World Health Organisation ("WHO") recommendations for cannabis; United States Pharmacopeial Convention ("USP"), African and South African standards for herbal products and extracts.

1.5.1 The wide range of references is necessary because no single source has all the parameters included in Qure's proposed standards.

1.5.2 Where multiple sources were available, Qure's recommendations are based on the stricter requirements – to ensure maximum safety.

2 Parameters that affect the quality of cannabis products

2.1 The following parameters are important in assuring the quality of cannabis and cannabis-related products:

2.1.1 Potency

2.1.2 Cannabinoid profile

2.1.3 Foreign materials

2.1.4 Heavy metals

2.1.5 Microbial impurities

2.1.6 Moisture content

2.1.7 Mycotoxins

2.1.8 Pesticides

2.1.9 Residual solvents

2.1.10 Terpenes

3 Why these parameters? How will testing help?

3.1 Potency

3.1.1 Potency is an indication of the strength of the CBD (cannabidiol) and THC (tetrahydrocannabinol) in a strain or product.

3.1.2 QURE PROPOSED STANDARD: As defined by the client or as required by law

3.2 Cannabinoid Profile

3.2.1 The Cannabinoid Profile is a sensitive and detailed test that identifies and quantifies cannabinoids in the plant or the product. It shows each of the cannabinoids as a percentage per mass of tested plant or product.

3.2.2 More than 120 different cannabinoids have been identified. The more well-known cannabinoids include: CBC, CBD, CBG, CBN, Δ8-THC, Δ9-THC and THCV.

3.2.3 QURE PROPOSED STANDARD: As defined by the client or as required by law

3.3 Foreign Material

3.3.1 Foreign matter can be hazardous or non-hazardous. Hazardous material includes foreign vegetable matter with allergenic or toxic properties; glass; metal; stones;

or physical contaminants such as insects, fecal matter, feathers, soil, hair.

3.3.2 It is important to ensure that there are no foreign contaminants, particularly in plants that are to be used for medicinal purposes.

3.3.3 TEST: Visual inspection by the grower or producer themselves.

3.3.4 QURE PROPOSED STANDARD: < 2% by weight of dried plant material (in line with USP and WHO for herbal medicines)

3.4 Heavy Metals

3.4.1 Metals that have a high density or atomic weight are called “heavy” metals. These include Arsenic (“As”), Cadmium (“Cd”), Lead (“Pb”) and Mercury (“Hg”).

3.4.2 The high degree of toxicity of these metals makes them significant with respect to human and animal health.

3.4.3 Depending on your location and the history of the soil, these metals may be present to varying degrees.

3.4.4 Cannabis and hemp roots will suck up and retain these harmful metals as well as other chemical contaminants, such as mining and industrial wastes, vehicle emissions, lead-acid batteries, fertilisers, paints and treated woods. (Hemp has been used successfully to decontaminate heavy metal polluted soils).

3.4.5 QURE PROPOSED STANDARDS:

Heavy Metals	
Arsenic (As)	< 2 ppm (in line with Chinese limits)
Cadmium (Cd)	< 0.3 ppm (in line with WHO)
Lead (Pb)	< 0.5 ppm (in line with California Medical Marijuana Bureau)
Mercury (Hg)	< 0.5 ppm (in line with China, Malaysia and Singapore limits for herbal medicines)

Heavy Metals	
Chromium (Cr)	≤ 2 ppm (in line with African Standard)
Copper (Cu)	≤ 150 ppm (in line with African Standard)

3.5 Microbial Impurities

3.5.1 Herbal medicines are all subject to microbial contamination from soil, air and water.

3.5.2 Microbial contamination of plant materials is mainly attributed to aerobic bacteria, enterobacteria (e.g. E. coli, Salmonella), yeast and mould.

3.5.3 The development of the contaminants is influenced by environmental factors such as temperature, humidity, harvesting, handling and storage.

3.5.4 In order to maintain the appropriate quality, safety and efficacy of these natural products, growers and producers therefore need to ensure the lowest possible level of contamination – and the way to show no / low levels of contamination is to test the products.

3.5.5 QURE PROPOSED STANDARDS:

Microbial Impurities	
Total aerobic count	<100 000 cfu/g
Yeast and mould	<10 000 cfu/g
Enterobacteria	<1 000 cfu/g
E. Coli	<100/g
Salmonella	Absent

3.6 Moisture Content (applicable to flower only)

3.6.1 Dried herbs last longer than fresh herbs because they have less water than fresh plant material.

3.6.2 Micro-organisms, especially mould, flourish in the presence of the right amount of water. When water is removed from plant material, the microbial growth cannot be sustained and the herb lasts much longer.

3.6.3 However, there needs to be a balance – you do not want flower that is too dry. It has been found that water content of 4% – 13% by weight is acceptable to minimise microbial growth.

3.6.4 QURE PROPOSED STANDARD: Water content at 4% – 13% of weight (incorporates guidelines from the Bureau of Medicinal Cannabis ("BMC"), California and the Association of Official Agricultural Chemists, known as AOAC.

3.7 Mycotoxins

3.7.1 Mycotoxins are toxic chemicals produced by fungi.

3.7.2 Contamination can occur during growth; with imperfect storage conditions, such as high humidity and high temperatures; or as a result of contact with insects or rodents.

3.7.3 Mycotoxins that naturally occur in South Africa are Fumonisins.

3.7.3.1 Aflatoxins are rare in South Africa, but could be found in imported products.

3.7.3.2 Deoxynivalenol ("DON") is a mycotoxin primarily produced by *Fusarium* fungi, commonly found in Europe and occurring predominantly in cereal grains.

3.7.4 QURE PROPOSED STANDARDS:

Mycotoxins	
Fumonisins	2 000 ppb
Total Aflatoxins	20 ppb
Aflatoxin B1: 5 ppb	5 ppb
DON	1 000 ppb

3.8 Pesticides

3.8.1 Despite the fact that pesticides are harmful, many growers still use pesticides to improve their yields.

3.8.2 Setting limits on the maximum levels of Pesticide Residues ensures that plants and their products are safe to use and ingest.

3.8.3 As a result of the wide range of pesticides used around the world, regions have diverse Pesticide Residue regulations.

3.8.4 For South Africa, Qure suggests testing for pesticides referred to in the African Standard for African Traditional Medicine ("ATM") and The South African Foodstuffs Act. Where discrepancies between the two were found, ATM was given precedence as it specifically applies to herbal medicines.

3.8.5 QURE PROPOSED STANDARDS:

Pesticide	Qure recommendation maximum ppm
Abamectin	0.01
Acephate	0.20
Acetamiprid	0.50
Aldicarb	0.07
Alpha-cypermethrin	0.05
Azinphos-methyl	0.50
Azoxystrobin	0.01
Benthiavalicarb-isopropyl	0.01
Beta-cyfluthrin	0.02
Bifenthrin	0.03
Boscalid	2.00
Bromide ion	400.00
Captan	15.00
Carbaryl	0.80
Carbendazim	0.10
Carbofuran	0.10
Carbosulfan	0.07
Cartap HCl	1.50
Chlorantraniliprole	0.50
Chlorothalonil	1.00
Chlorpyrifos	1.00
Chlorpyrifos methyl	0.30
Clothianidin	0.01
Copper oxychloride & other salts	20.00

Pesticide	Qure recommendation maximum ppm
Cyantranilipole	0.50
Cyfluthrin	0.03
Cyhalothrin	0.03
Cypermenthrin	0.10
Deltamethrin	0.03
Demeton-S	0.20
Diazinon	0.10
Dichlorophen	0.50
Dichlorphos (DDVP)	0.10
Dicofol (Dichlorobenzophenone)	0.10
Difenoconazole	0.10
Diflubenzuron	0.01
Dimethoate	0.50
Dimethomorph	0.01
Dimethyl didecyl ammonium chloride	0.20
Dinocap	0.50
Diquat	0.05
Disulfoton	0.05
Emamectin	0.01
Endosulfan	5.00
Epoxiconazole	0.01
Ethion	5.00
Ethoprop(hos)	0.01
Fenbutatin Oxide	0.20
Fenhexamid	5.00
Fenitrothion	1.00
Fenvalerate and Esfenvalerate	0.03
Fipronil	0.05
Fludioxonil	0.02
Fluopicolide	0.05
Fluquinconazole	0.10
Flusilazole	0.01

Pesticide	Qure recommendation maximum ppm
Flutriafol	0.10
Folpet	0.50
Furfural	0.50
Glyphosate	2.00
Guazatine	2.50
Hydrogen Phosphide	0.01
Indoxacarb	2.00
Imazalil	2.00
Iprodione	0.10
Kresoxim-methyl	0.05
Lambda-Cyhalomethrin	0.10
Lufenuron	0.10
Malathion	1.00
Mandipropamid	0.01
Mercaptothion	3.00
Metalaxyl	5.00
Methamidophos	0.10
Methiocarb	0.07
Methomyl	0.10
Methoxyfenozide	1.00
Metrafenone	0.50
Mevinphos	0.10
Milbemectin	0.01
Novaluron	0.05
Omethoate	0.01
Oxydemeton-Methyl	0.20
Parathion	0.20
Parathion-methyl	5.00
Permethrins	0.05
Phenthoate	7.00
Phorate	0.10
Phosalone	2.00

Pesticide	Qure recommendation maximum ppm
Piperonyl butoxide	5.00
Pirimicarb	5.00
Pirimiphos-methyl	0.50
Profenofos	0.07
Propioconazole	0.02
Propyzamide	0.10
Proquinazid	0.20
Prothioconazole	0.20
Pyraclostrobin	0.50
Pyrethrins	1.00
Pyridalyl	0.01
Pyrimethanil	0.50
Quinoxyfen	0.50
Quintozene	0.02
Spinetoram	0.05
Spinosad	0.02
Spirodiclofen	0.01
Spiroxamine	0.05
Sulfoxaflor	0.05
Tau-fluvalinate	0.05
Tebuconazole	0.50
Thiacloprid	1.00
Thiamethoxam	0.02
Triadimefon and Triadimenol	0.50
Triazophos	0.07
Trichlopyr	0.10
Trifloxystrobin	0.10
Trifluralin	0.05
Vinclozolin	0.05
Zoxamide	1.00

3.9 Residual Solvents

3.9.1 Residual Solvents are residues of organic solvents used to process herbal extractions. Testing for residual solvents gives an indication of whether or not the extraction solvent was removed properly.

3.9.2 Solvents are classified into three categories, based on their potential to cause harm.

3.9.2.1 Class 1 solvents should be avoided. They include carcinogens, toxic substances and environmental hazards, for example, benzene, carbon tetrachloride, dichloroethane.

3.9.2.2 Class 2 solvents have limited toxic potential. Examples include, methanol, hexane, chloroform. Limits for daily exposure to each of these have been individually determined.

3.9.2.3 Class 3 solvents have low toxicity. However, the residual solvent should not exceed 0.5% of the final medicinal product. Examples include ethanol, acetone, isopropanol, butane.

3.9.3 QURE PROPOSED STANDARDS:

3.9.3.1 Class 1: Absent

3.9.3.2 Classes 2 and 3 – as per table below

Solvent	Class	Products for inhalation Maximum (ppm)	All other products Maximum (ppm)
Acetone	3	750	5 000
Acetonitrile	2	60	410
Butane	3	800	5 000
Chloroform	2	2	60
Cyclohexane	2	20	3 880
Dichloroethane (1,2-Dichloroethane)	2	2	5

Solvent	Class	Products for inhalation Maximum (ppm)	All other products Maximum (ppm)
Dichloromethane (DCM, Methylene chloride)	2	125	600
Diethyl ether (Ether, Ethyl ether)	3	500	5 000
Ethanol	3	1 000	5 000
Ethyl acetate	3	400	5 000
Heptane	3	500	5 000
Hexane	2	50	290
Isopropanol (Isopropyl aclohol, Isoprop)	3	500	5 000
Methanol	2	250	3 000
Pentane	3	750	5 000
Propane	3	2 100	5 000
Toluene	2	150	890
Trichloroethene (Trichloroethylene)	2	25	80
Xylene	2	150	2 170

3.10 Terpenes

3.10.1 Terpenes are fragrance molecules. They typically occur in amounts of less than 1% in cannabis flower, but even in these low quantities they contribute significantly to the flavour experience and medicinal value.

3.10.2 Terpene analysis gives the quantity of each terpene present in the sample.

3.10.3 Terpene analysis enables plant cultivators, processors, healthcare providers, consumers and researchers to:

3.10.3.1 Identify terpenes;

3.10.3.2 Ascertain which terpenes are best suited in medicinal applications;

3.10.3.3 Build information on flavour profiles between growth batches – facilitating

consistency and allowing growers to selectively modulate the terpene ratios of their strains so as to maximise desired benefits;

3.10.3.4 Provide proof that the product/s contains certain amounts of specific terpenes; etc.

3.10.4 QURE PROPOSED STANDARDS: No standards are necessary for terpenes in cannabis, as each grow will have its unique combination.

Qure
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