A Clinical Framework for Evaluating Cannabis Product Quality and Safety

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Introduction

- Increasing cannabis use and product availability warrants the need for healthcare providers (HCPs) to be knowledgeable in assessing cannabis quality and safety (CQS) in clinical practice to mitigate potential cannabis-related harms.[1]
- Determining whether a product is regulated within the region is key in assessing overall quality and safety.
- Regulated products have greater quality control including independent testing, contamination mitigation, and concentration limits.
- We developed a clinical framework for evaluating the quality and regulation level of cannabis products.

Cannabis Quality & Safety Framework

Q1. What type of product is it?
a. Are there any concerns with the specific product type?
Q2. Does the product have appropriate labelling?
b. Does it show the name of the product?
c. Does it show the name of the producer/distributor?
d. Is the company's contact information listed (website, phone, email)?
e. Does the product have health warning labels? (e.g. THC logo)
f. Are there any additional warnings?
g. Are optimal storage details listed?
Q3. What is the listed cannabinoid content?
h. If dried flower or inhaled concentrates, is THC and/or CBD listed (% or mg/g)?
i. If ingestible oils, is the mg/mL of THC and/or CBD listed?
j. If edibles, if there a "serving size" or "dose" listed?
k. If topicals/creams, is there a THC and/or CBD amount listed (mg, mg/mL, mg/g)?
Q4. What are the listed product/manufacturing details?
l. Is there a package date?
m. Is there an expiry date (including "no expiry date")?
n. Is there a lot/batch number?
o. Is the net weight/volume listed?
p. If the product is an oil, edible, or vape, are the non-cannabis ingredients listed?
q. Is the decontamination method specified (label or company website)?
r. Is there evidence of third party testing (label or company website)?
Q5. Is packaging in line with regional regulations?
s. Does packaging have a security feature to indicate whether the seal is broken?
t. Does the product have child-resistant packaging?
u. Does the packaging and labeling appeal to children/adolescents (cartoon images, vibrant colours, packaging similar to candy etc.)?
v. Is the product labeled as being within the regional allowable THC limits?

Product Type

- Common product types for medical use are oil formulations or dried cannabis flower

Cannabis concentrates

- Extraction process may introduce harmful solvents and contaminants
- Cannabis concentrates may contain up to 80-90% THC (e.g. shatter)
  - These high potency products are associated with increased risk of adverse events (e.g. unintended, excessive impairment)[2,3]

E-cigarette or Vaping Products

- Vape pens, dab pens, E –cigarettes, "Electronic nicotine delivery systems (ENDS)" etc. use cannabis cartridges, **not** dried flower
- Significant health risk known as E-Cigarette or Vaping Product Use-Associated Lung Injury (EVALI) due to high vitamin E acetate levels[4]

  **No evidence for EVALI risk for vaping with dried cannabis

Dried Flower

Smoking

- Inhalation of toxic combustion substances (Polycyclic Aromatic Hydrocarbons (PAH's), ammonia, carbon monoxide, carcinogens, tar)

Vaporization

- Combustion-free (convection) cannabis vaporizers offer a **safer** alternative to smoking without creating toxic by-products

Product Types Generally Not Recommended for Medical Use

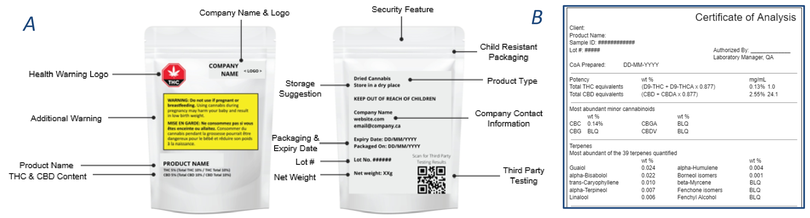
(A) Cannabis concentrates, (B) E-cigarette and vaping products that use liquid cartridges, (C) smoked cannabis product

Product Labelling

Regulated Cannabis Product Requirements
1. Product's name
2. Producer and/or distributor
3. Company's contact information (name, telephone number, email address)
4. Regulatory status (e.g. licensed cannabis producer or retailer)
5. Adherence to local regulatory and product testing guidelines should be verified
6. Indications of optimal storage requirements
7. Warning symbols/signs
8. Standardized cannabis symbol
9. THC & CBD content
10. Product/manufacturing details (e.g. lot #, batch #, COA, third party testing)

Regulated Product Labelling

Regulated product labelling (A). Certificate of Analysis should be available via the company website, or QR code on the package (B).



Cannabinoid Content

- Regulated, legal products in Canada are required to contain no more than the listed THC limit.
- No CBD limits for products in Canada

Product	Limit
Dried Flower	~30% THC
Edible Cannabis (Food/Drinks)	10mg THC per package
Cannabis Extract (Ingested)	10mg THC per unit (capsule/dispensed amount) 1000mg THC per package or bottle
Cannabis Extract (Inhaling)	1000mg THC per package
Cannabis Topical	1000mg THC per package

Manufacturing Details

Third Party Testing

- Third party testing for pesticides, microbes and heavy metals is a crucial step in quality control and product safety for each lot/batch.
- Gamma radiation is the preferred decontamination process

Certificate of Analysis (COA)

- Best practice for products to have a certificate of analysis (COA) from a third party laboratory showing results of quality control testing.

Regional Regulation Adherence

Regulated cannabis has regional packaging specifications for:

- THC warning symbol
- Font and colour of packaging
- Specific wording of warnings
- License number
- Usage instructions
- Security features

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