

Laboratories

USP-ASTM Europe-America Workshop

**Harmonisation of cannabis quality standards for
medical and scientific use**

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Controlled drugs and the UN Conventions

A country's drug use estimates and reporting is based upon quantifying national medical drug use requirements, and the yields of domestic production (*cultivation or manufacturing*).

Analytical accuracy and harmonisation of standards is essential to all countries licencing, monitoring and reporting activities.

Accuracy and harmonisation is essential to our international agreements, to transitional trade, and the validity of cannabis as a medicine.

Laboratories are at the centre.

Analytical laboratories

These laboratories form an essential component of the production and supply chain, and the wider quality standards framework.

Analytical inconsistencies

Around the globe the industry and regulatory authorities are currently challenged by:

- irregularities of laboratory practices,
- inconsistent analytical techniques and methodologies,
- variable quality of reference materials and standards,
- variability in samples and sample preparation.

Hence, materials and products tested in one site may differ from another.



Qualification and audit

Industry need to have contractual quality agreements that specify the quality standards that must be applied to testing.

This requires laboratories to take part in supplier qualification programmes and audits.

Validation

Variation in instruments and by laboratory personnel will introduce a small amount of variability, which is amplified with lab-to-lab differences – *this is an issue identified for cannabis.*

External quality-control assurance – *testing identical samples in a variety of laboratories to compare results*

Who will act as the lead laboratory in cross-laboratory validation?



Sampling and sample preparation

Sampling should take into account the distribution of compounds in cannabis herbal material, and represent the batch (including chemovar).

The sampling procedure must not be deliberately manipulated to obtain the most or least 'potent' material.

The homogeneity of the sample being tested is essential.

Reducing the particle size of the dry cannabis herbal material without affecting the nature of the analytes can be difficult.

Pulverising and sieving cannabis material may lead to significant loss of active components by the sticking of glandular trichomes to sieves, blenders, cutters, etc..

Particularly with high potency cannabis strains.

Harmonisation of sample preparation methodology is critical.



LoD vs a_w

The methods for determining moisture / water content of cannabis inflorescence include Loss on Drying (LoD) and Water Activity (a_w).

A water activity (a_w) at between $0.60 \pm 0.05 a_w$ is applied to cannabis herbal material to prevent degradation from excessive drying (below $0.55 a_w$) or microbial growth (above $0.65 a_w$).

LoD is used to determine the moisture content and to calculate the cannabinoid content on a weight for weight basis (eg, % THC w/w) - this quantitative data is used for industrial contracts and licensing.

LoD using the Karl-Fischer method may not account for other volatile substance, (eg, terpenes), which constitute the total weight of the cannabis material sample.

Ph Eur 2.2.32: Loss-on Drying measures the total change in weight of a material when the sample is dried (all volatile components), Karl Fischer Titration measures only water content (water-specific), Halogen Moisture Analysis (all volatile components).



Future thinking...

Regulatory and market developments

Many more laboratories across the globe are now required to both qualitatively and quantitatively identify cannabis and derived products.

For Government and Forensic Laboratories, this means:

- **identifying and categorising when (i) a medicine** is a controlled drug, (ii) is a substandard, falsified product or substance, or, (iii) is an illegal recreational drug and/or a diverted medicine,
- they act as an independent laboratory (approved laboratory) that provides 'forensic' or 'compliance' services in case of (i) a **dispute about medicine quality or label claims**, or (ii) criminal case evidence,
- they may act as the **lead in analytical proficiency** (cross-laboratory validation) and laboratory certification processes and provide independent advice on analytical methodology.



Global monograph – harmonisation

A globally adopted compliance-oriented monograph.

Such a monograph must consider the factors of:

- cost (affordability),
- value, fit-for-purpose (practical, applicable and reliable), and
- adoption (taken up by industry and regulators around the globe).

At the national level, in many countries, chemical analysis down to low thresholds may not be possible given a lack of appropriate, cost effective identification techniques, and because of available resources to achieve this long-term.

