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Accreditation Perspectives for the Analysis of Cannabinoids

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INTRODUCTION

Analysis of cannabinoid concentrations in cannabis products contributes to ensure quality, safety and efficacy.

There is a need to increase access to accredited methods for determination of Δ9-tetrahydrocannabninol (THC) in cannabis products so as to provide robust quality checks for cannabis products available.

AIM

Development and accreditation through International Organisation for Standardisation/ International Electrotechnical Commission (ISO/IEC) 17025 for analytical methods for determination of THC in oil using high-performance liquid chromatography with ultraviolet detection (HPLC-UV) is being sought.

METHOD

Research is conducted at the Pharmaceutical Technology and Synthesis Laboratory at the Department of Pharmacy, University of Malta.

Sample preparation procedures and HPLC-UV analytical method parameters for determination of THC in oil were compared and selected according to which gave the best results in terms of Area Under the Peak for THC with the highest reproducibility.

Analysis of THC in oil was conducted using an Agilent 1260 Infinity HPLC. ISO/IEC 17025 requirements were identified.

Quality system consisting of documents and records required by ISO/IEC 17025 and Standard Operating Procedures (SOP) related to the developed method were elaborated.

Equipment used for sample preparation and analysis was calibrated by accredited calibration laboratories.

RESULTS

Dilute and shoot procedure using a ratio of 1:500 THC in oil and methanol was selected as the sample preparation method.

Analysis was conducted at 225nm using mobile phase made up of acetonitrile and phosphoric acid and a reversed-phase carbon-18 column.

Updated documentation consisted of SOPs related to training, delivery and storage of chemicals and analytical procedure.

Implemented documentation consisted of SOPs for equipment, instrumentation and records related to impartiality risk assessments, evaluation of measurement of uncertainty, quality policy and audit plan (Table 1).

Table 1: ISO/IEC 17025 Mandatory Documentation List

Developed ISO/IEC 17025 Mandatory Documentation	
Quality Manual	SOP to Address Risks and Opportunities for Improvements
Impartiality Risk Assessment	Corrective and Preventive Action SOP
Equipment Calibration Risk Assessment	Laboratory Site Plan
Test Report Template	Organisational Chart
SOP to Address Complaints and Feedback	Revision of Documentation Plan
Internal Audit SOP	Cleaning Log

CONCLUSION

Accreditation of method for determination of THC in oil would lead to the use of robust analytical method with generation of reliable data and test results.