

New Technologies in the Fight Against Falsified Medical Products: X-ray Powder Diffraction - Possibilities and Drawbacks

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Belgrade, Serbia

Falsified Medical Products

Deadly new drugs found in fake medicines in the UK

29 October 2024

Alex Homer
Shared Data Unit

Navtej Johal

BBC News, Midlands correspondent

UCLA Health

Find Care

Patient Resources

Treatment Options

Locations

Discover

Find a

News & Insights

Counterfeit pills sold in Mexican pharmacies found to contain fentanyl, heroin, and methamphetamine

Global State

Prior data (IMPACT report) estimated $\geq 30\%$
Current information (WHO) $\geq 10\%$

Contaminated cough syrups death toll passes 300 in four months



BY SANJAY KUMAR | 14 FEBRUARY 2023



SOUTH DAKOTA
DEPARTMENT OF HEALTH

Topics

Programs

LI

News

Fake Pills Kill: The Increasing Danger of Fentanyl

Half a million lives lost to fake medicines in sub-Saharan Africa: UN

UN says 605 tons of trafficked medical products were seized in West Africa alone between 2017 and December 2021

Screening Technologies for Detection – handheld devices

TLC (testing kits)



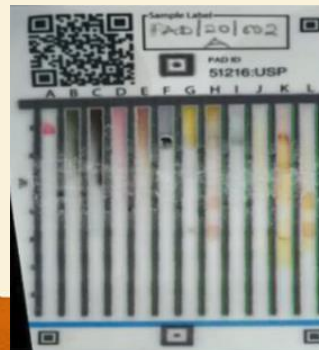
Raman spectroscopy



NIR spectroscopy



PADs (paper analytical devices)



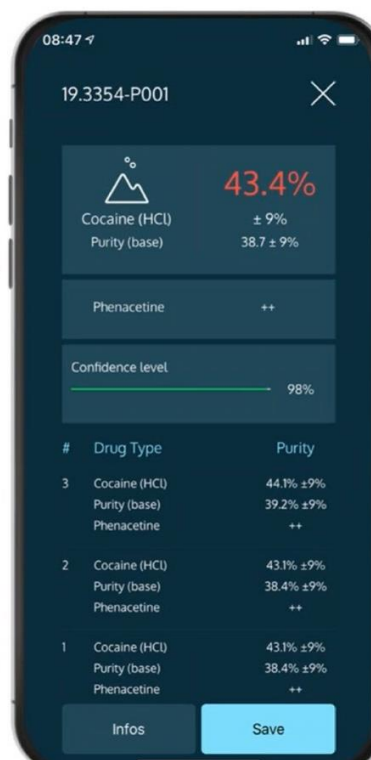
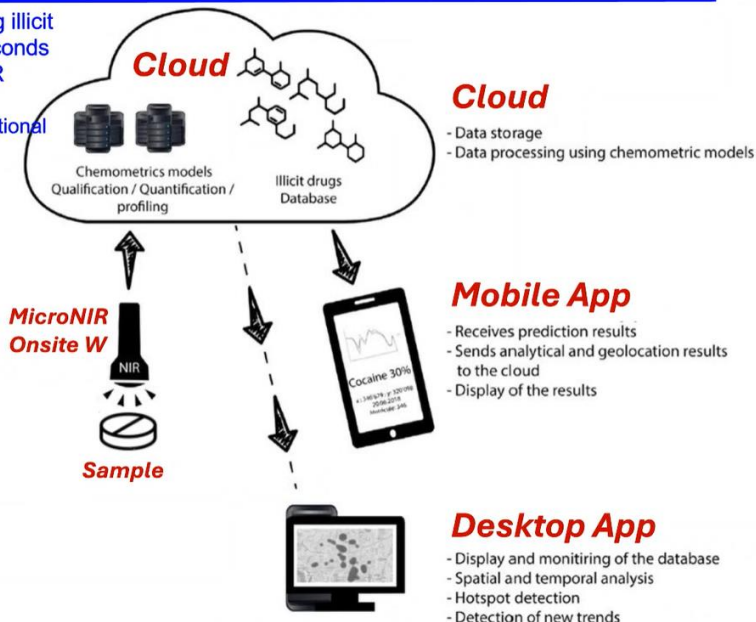
Screening Technologies for Detection – handheld devices

Close to an „ideal“ technology? Illicit drugs screening by Swiss police

Coppey *et al.*: Providing illicit drugs results in five seconds using ultra-portable NIR technology.
Forensic Science International 317 (2020) 110498



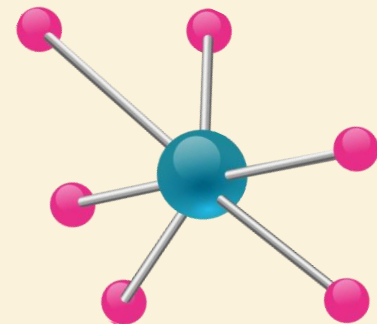
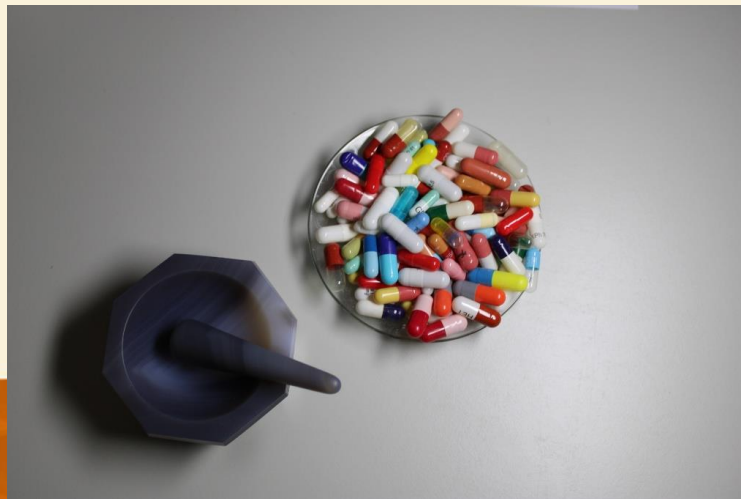
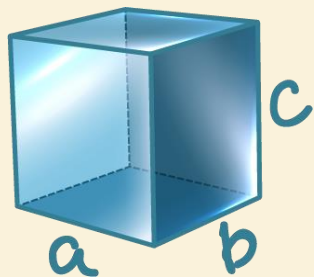
**NIR spectrometer
MicroNIR Onsite W**



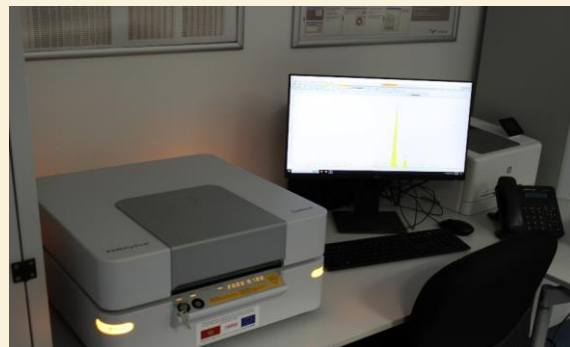
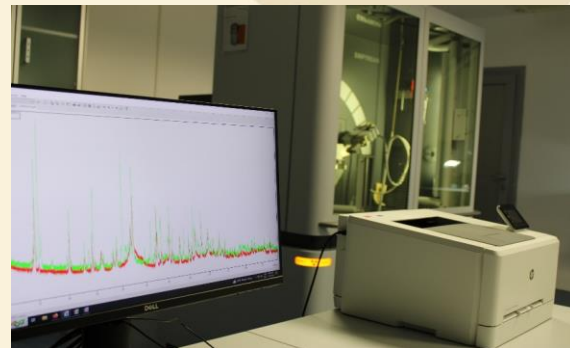
Laboratory of the Institute for Medicines and Medical Devices of Montenegro

The laboratory instruments were funded through the EU Instrument for Pre-Accession Assistance (IPA II, 2014–2020) under Negotiation Chapter 1 – Free Movement of Goods, and were delivered in December 2020.

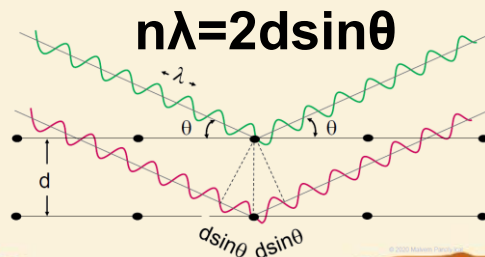
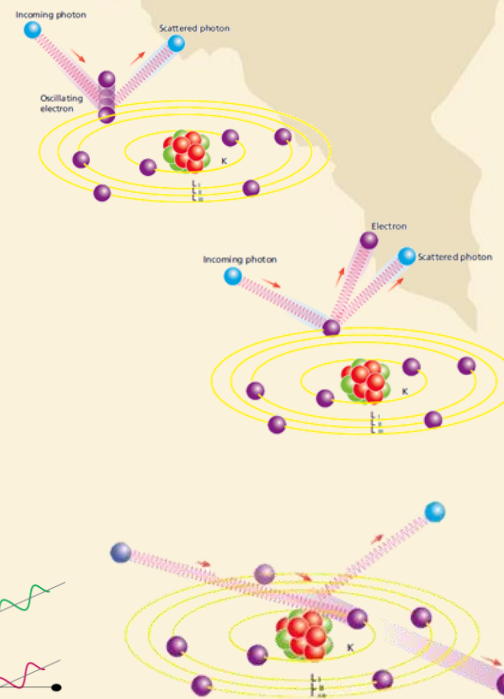
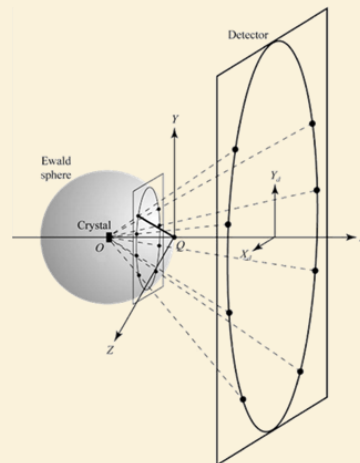
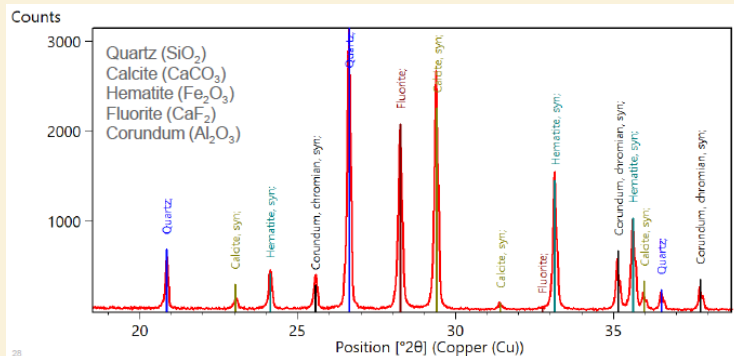
The equipment is intended for the detection of substandard and falsified medicines on the Montenegrin market using X-ray powder diffraction (XRPD) and X-ray fluorescence (XRF) techniques.



Laboratory of the Institute for Medicines and Medical Devices of Montenegro



X-ray Powder Diffraction: The Fundamentals



	X-Ray Diffraction	X-Ray Fluorescence
Atomic structure	Yes	No
Elemental composition	No (indirect)	Yes
Polymorph discrimination	Yes	No
Fingerprinting	Yes	Yes (for elements)
Database size	1,000,000+	Not applicable
Quantitative analysis	Yes	Yes
Speed	Minutes	Minutes

XRD Applications in Pharmaceutical Analysis



API identification

Confirms identity of crystalline patterns against reference databases and detects adulterations



Polymorph screening

Distinguishes between different polymorphs of a molecule, which can dramatically affect its therapeutic efficacy



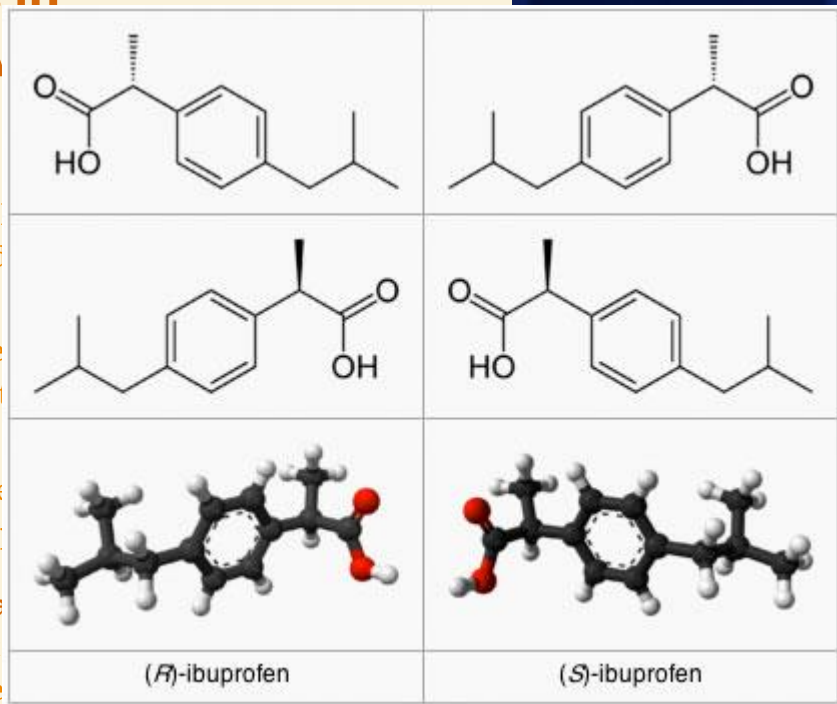
Excipient analysis

Identifies crystalline excipients and detects substitutions that may compromise product performance



Mixture characterization and adulteration detection

Analyzes multi-component mixtures to identify components and detect undeclared ingredients



XRD Technology: Possibilities and Drawbacks

Pros

Non-Destructive Analysis

Samples remain intact after analysis, enabling additional testing or evidence

Definitive Identification

Provides unambiguous crystalline phase identification with high specificity and

Minimal Sample Preparation

Requires simple grinding and mounting, reducing time and potential for

Quantitative Capability

Can estimate relative proportions of crystalline phases and total amorphous content in mixtures through Rietveld refinement

Solving crystal and molecular structure

The most advanced and challenging field of XRPD

No reference materials needed

The technique requires databases, that can be used to analyze samples without reference materials

Cons

Amorphous Materials

Cannot identify or characterize non-crystalline substances, limiting utility for some formulations

Equipment Cost

High initial capital investment and maintenance requirements restrict accessibility in resource-limited settings

Expertise Required

Data interpretation demands specialized training and experience for accurate pattern analysis

Interpretation Time

Measurements typically require 60 minutes per sample, and interpretations can be very lengthy

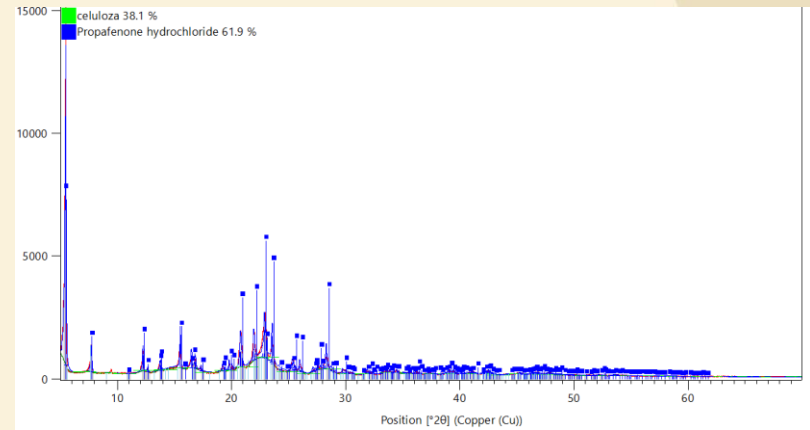
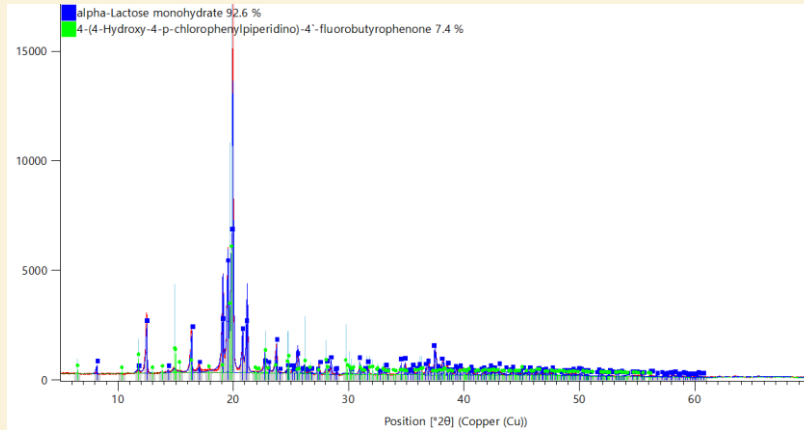
Safety concerns

Due to X-ray radiation, it is important to conduct regular checks for equipment and medical checks on personnel

Solid samples only

One of the biggest drawbacks, as liquid samples are not an option

XRD Technology: Possibilities and Drawbacks



Thank you for your attention

