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Rapid identification of counterfeit pills by ATR FT/IR analysis of crushed samples

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Abstract

Introduction: Counterfeit medicines are now a serious global problem which pose ever-increasing threats to public health. The manufacture and supply of medicines is a global business and the shipment of millions of dosage forms presents huge challenges to ensuring the safety of the medication reaching the patient. According to the WHO[1] counterfeits may have: no active ingredients present, the wrong level of ingredients, the wrong ingredients, high levels of contaminants or be in counterfeit packaging. This research examines the possibility of replacing sophisticated laboratory tests with simpler and therefore faster bench top tests.

Methods: Attenuated Total Reflection (ATR) FT/IR spectroscopy has been investigated as a replacement technique to the conventional methods cited in the British Pharmacopoeia BP 2012[2]. The BP methodology requires the sample to be crushed, solvent extracted, the solvent evaporated and the residue prepared as a KBr disc prior to running the IR fingerprint for identification. Several hours are required for this procedure. ATR FT/IR analyses only require the sample to be ground to a powder which is then spread over the reflection cell to allow the fingerprint spectrum to be recorded. The time scale for these measurements is several minutes only.

A range of samples of caffeine, paracetamol, atenolol and sildenafil were subjected to ATR FT/IR analysis in order to investigate:

- The effects of different excipients
- The ability to identify the presence of the target drug at different doses
- The ability to identify the presence of more than one target drug in tablets with multiple actives.

These were studied as standards in conventional magnesium stearate/dibasic calcium phosphate excipients and in different therapeutic 'pill' dosage forms.

Results: The ATR FT/IR analyses have proved to be much faster that the BP methods and have also demonstrated the provision of high quality spectral fingerprint data without the need for extensive laboratory training of staff. Not only was the ATR FT/IR system able to identify single and mixed components the detection capabilities of this system were better (2X) than those reported by Khinchi et al [3] for formulated mixtures.

Conclusions: The ATR FT/IR system has demonstrated the ability to confirm the presence of both good and counterfeit materials in simple selected tablet dosage forms. Paracetamol, caffeine and atenolol all produced identifiable fingerprints at levels down to ca 4.0% in pill formulations. A more extensive survey is currently being undertaken.

Biography

Graham Lawson's expertise is instrumental analysis in such disparate areas as environmental exposure in the polymer industry, the identification of migrants from food packaging and factors influencing drug delivery in clinical applications. The unifying themes are the detection of ultra low levels of contamination and the protection of people from adverse exposures. He was co-opted onto a NATO special studies group on the Stand-off detection of radiation. His current research interests include novel analytical techniques applied to blood spot analyses and to counterfeit drug detection.