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Review Article

FTIR Spectroscopy Used in Adulterated Drug Analysis

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Abstract

The battle against adulterated medications has grown to be a high-priority problem involving many players due to the harm to human health. To chemically analyze counterfeit materials and determine their level of patient risk, analytical laboratories participate in new investigations. Several techniques can be used to obtain specific information about the organic and inorganic composition, the presence of active ingredients or impurities, or the crystalline arrangement of the compound in the formulation. With the development of safer, more effective medications over the past few decades, the pharmaceutical industry has gained a major lead. Because of their high price, modern pharmaceuticals are always more susceptible to falsification or imitation. The public's health is at risk due to inadequate variants of the original product, which frequently lead to treatment failure. Pharmaceutical items, whether chemical or herbal, are increasingly being characterized using infrared spectroscopy to track changes and identify fraudulent modifications. This review presents some of the most relevant papers related to the use of infrared spectroscopy in the analysis of adulterated drugs (chemical and herbal) products, published between 2021 and 2026.

Keywords: Adulterated Drugs; Analytical Methods; Infrared Spectroscopy

Introduction

The World Health Organization (WHO) defines adulterated drugs as medications that are manufactured and distributed with the intention of falsely claiming their source, efficacy, or validity is considered a counterfeit, or those medications that are deliberately and fraudulently mislabeled with respect to identity and source. It can contain incorrect dosages, potentially dangerous substances not indicated on the label, or no active ingredients at all [1].

The global market is expected to be worth between $200 billion (CHF 180 billion) and $ 432 billion annually, according to analysts. According to the WHO estimates, 10 % of medications are counterfeit [2]. Counterfeit drugs seriously endanger patients by decreasing the effectiveness of medical treatment and endangering lives all around the world. Drug resistance, therapeutic failure, and, in the worst situations, even death can result from long-term use of fake medications [3].

Ethical pharmaceutical companies collaborate with regulatory bodies in several countries. These conduct their own "market sweeps" and regularly share information with law enforcement to help eradicate all counterfeit items and shut down illegal enterprises. Some of the most important drug regulatory organizations operating in different nations are: FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), CDSCO (Central Drugs Standard Control Organization), MHRA (Medicines and Healthcare products Regulatory Agency, in the UK), TGA

(Therapeutic Goods Administration, in Australia), Health Canada, ANVISA (Agência Nacional de Vigilância Sanitária, in Brasil).

In the past, a wide range of analytical techniques has been used to evaluate the authenticity of pharmaceutical preparations while accounting for the Active Pharmaceutical Ingredient (API) content. The primary steps are described in the pharmacopeia texts. The most difficult techniques include gas chromatography [4], high-performance liquid chromatography with UV detection [5-7], liquid chromatography coupled with mass spectrometry [7,8], and other techniques [9,10]. Although these methods are very useful for identifying the examined material and offer extra information about the studied samples, they are time-consuming and require careful sample preparation. They also need high-quality staff and expensive equipment.

Generally speaking, spectroscopic techniques are less complicated, nondestructive, and more affordable than chromatographic techniques. Considering these benefits, the spectroscopic method appears to be the ideal option for a quick examination of various samples. However, this method cannot give all the information concerning the chemical constituents of the substance or identify its distinctive chemical markers.

Techniques using infrared spectroscopy are practical and widely applicable for drug screening [11-15].

Spectroscopy examines the relationship between matter and electromagnetic radiation, specifically light. Information regarding the structure of an atom can be gathered through a variety of spectroscopic methods. In infrared spectroscopy, a sample's molecules absorb a specific frequency of light, changing their vibrational and rotational energy levels. By identifying the absorption of infrared radiation, IR absorption spectra can be acquired. Molecular vibration is monitored in the infrared region (IR) to classify sample functional groups. Each functional group (or structural characteristic) has a single vibrational frequency [16].

This review discusses the analysis of adulterated drugs using infrared spectroscopy. After providing an overview of the concept of adulteration, I will present several studies released between 2021 and 2026 that investigated contaminated pharmaceutical products (chemicals and herbal) using infrared techniques.

Adulteration concept

In 1985, adulteration was first brought up at the World Health Organization's (WHO) conference of specialists on rational drug use in Nairobi, Kenya [17]. The issue has increased dramatically after this summit.

Various types of counterfeit drugs pose unique challenges to the pharmaceutical industry and jeopardize the health and welfare of dependent patients. These substances are a dangerous byproduct of illegal behavior. The various categories of fake medications are listed below [18]:

- **Substandard drug:** Drugs that don't meet the strict quality requirements established by regulatory agencies are considered substandard. From subpar raw materials to subpar quality control, the discrepancy may arise at any stage of the production process. These medications may be hazardous or ineffective if they contain the wrong amounts of contaminants or active substances [19].
- **Falsified Medications:** Medications that have been falsified involve either fabricating the source's identity or both. These goods might include all the components required, but they might also be packaged fraudulently, have phony labeling, or be unlawfully branded. This kind of fake works especially well because it could be hard to find without close inspection [18,20].
- **Pure Counterfeit Drugs:** Pure counterfeit medications are adulterants and have no medicinal benefit. These drugs are meticulously created to resemble real pharmaceuticals, often down to the very last aspects, like labeling and packaging [21].
- **Expired or Stale Drugs:** Similarly, stale or expired drugs may be repackaged and sold by medicine counterfeiters. Despite the medications' outward true nature, their usefulness has decreased, affecting patients who are dependent on their therapeutic effects [22].
- **Misbranded Drugs:** These medications involve false labeling methods, such as unclear instructions, incorrect dosing directions, or excessive therapeutic claims. Counterfeit medications may have unexpected health effects and undermine patient trust, even when they are not entirely false [23].

- **Adulterated Drugs:** The deliberate insertion of dangerous ingredients into drugs is known as adulteration. This could include the use of hazardous pollutants, inappropriate active substances, or excessive amounts [24]. Modern analytical techniques frequently detect contaminated medications, which have been associated with significant health hazards [25].

As shown in Figure1, manufacturing and distribution of FMs involves a more or all of the following four steps, which may not take place in this order or at the same location: (i) acquiring and transporting excipients and other raw materials to the manufacturing site; (ii) manufacturing the finished product; (iii) manufacturing the packaging; and (iv) laundering into physical or virtual sales channels [26]. The graphical illustration of the manufacturing process of counterfeit medications and the source of their biological and chemical signatures is presented. In this figure, the various backdrop colors correspond to different manufacturing phases and distinct geographical regions. The sequential addition of variously colored signatures indicates that each production process may introduce new chemical and biological signatures to counterfeit medications. The locations shown are merely meant to serve as examples [26].

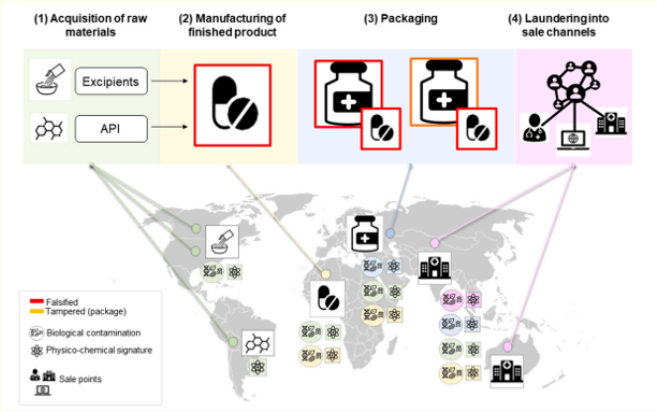

Figure 1: A graphical illustration of the manufacturing process of counterfeit medications and the source of their biological and chemical signatures (permission request from file [26]).

Counterfeiting targets every type of pharmaceutical product with strong consumer demand and appealing revenue potential [27]. Due to the potential for huge profits in their markets, mostly through online purchasing, the United States and Europe (especially the United Kingdom) have experienced an increase in the confiscation of counterfeit medications. Due to low production costs and rising demand for inexpensive medications, the counterfeit pharmaceutical trader remains a highly profitable industry with sophisticated international networks.

The subject of drug adulteration and authenticity has been the subject of a substantial amount of research in recent years. Between 2015 and 2019, approximately 2,700 papers were published, while between 2020 and 2026, around 2,500 papers were published (as presented in Figure 2). The results presented here are a consequence of an investigation using the keywords “adulterated drugs” vs. “adulterated drugs infrared analysis” in ScienceDirect journals.

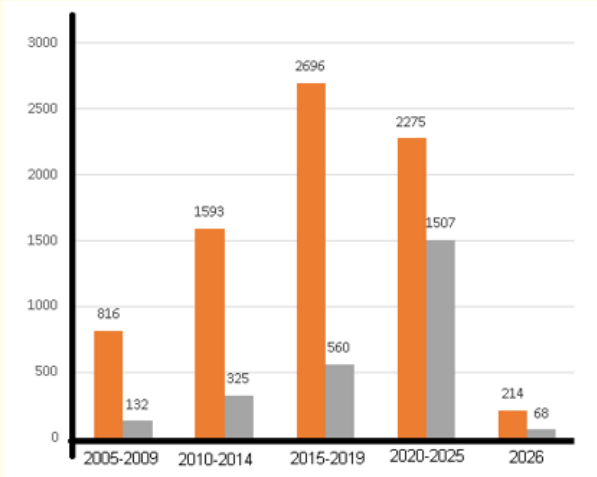

Figure 2: Temporal progress of reported persons on the adulteration of drugs in recent years.

(orange bars (adulterated drugs) vs. gray bars (infrared analysis methods)).

During the studied period, several reviews were published [25,28-32]

Since the 1960s, FTIR techniques have been extensively employed for both qualitative and quantitative investigations

[33,34]. Since early 1987, FTIR fingerprint spectra have been used in the field of herbal medicine, although they are less common than CM [35]. The complexity of spectra and their interpretation has limited the use of FTIR techniques to this point [36]. However, FTIR spectroscopy offers a broad range of opportunities for this type of drug research when combined with chemometric techniques [37,38].

Continuing a previous personal paper [39], Lawson., *et al*. [40] applied the ATR-FTIR technique (Attenuated Total Reflectance-Fourier Transform Infrared) to differentiate between authentic and counterfeit paracetamol tablets.

The reference spectra for pure paracetamol (upper) and the data from the analysis of the powder from a crushed paracetamol tablet (lower trace) closely match, as seen in Figure 3. The specific agreement between the spectra indicates that paracetamol exists in the tablet formulation. Examining all of the distinctive fingerprint spectra of the drug excipients, it was found that there were some potential interference peaks between 1700 and 1400 cm^{-1}, which should be avoided. Different sides of the same table were examined using the ATR-FTIR approach for improved results (blue and red traces in Figure 3). The crushed powder samples indicated in black in Figure 4 produced a stronger and more consistent signal.

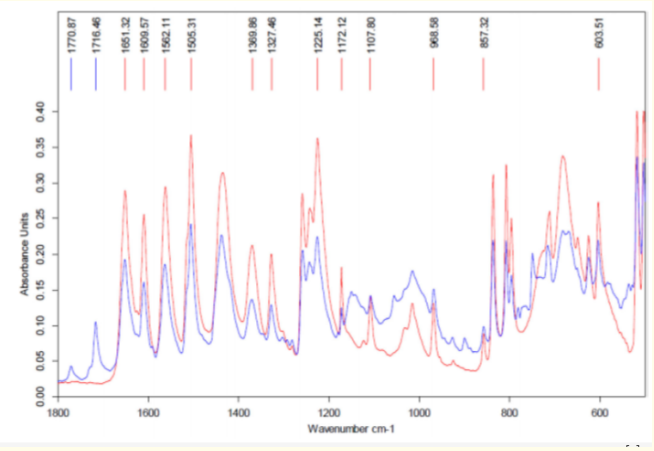

Figure 3: Overlay of pure paracetamol (Upper) and a paracetamol tablet sample Tharfenac (Lower).

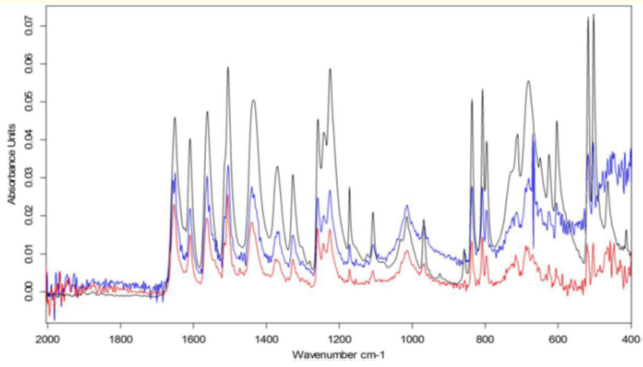

Figure 4: Paracetamol tablet crushed (Black), Whole tablet top (Blue), Whole tablet bottom (Red).

Pharmaceutical companies no longer create the majority of medications in their own countries; instead, contract manufacturers or manufacturing facilities in nations with lower transportation costs do so. This not only makes it challenging to track them down, but it also allows criminal groups to impersonate them covertly. These factors are making it more challenging to pinpoint the precise source of medications. Using several spectroscopic techniques, such as nuclear magnetic resonance and near- and mid-infrared spectroscopy, in conjunction with multivariate data analysis, Becht., *et al*. [41], tried to demonstrate how precisely this can be done. Using only measured spectra and principal component analysis (PCA) and linear discriminant analysis (LDA), they attempted to determine the country of manufacturing and the origin of the medications in this investigation. Paracetamol formulations have been utilized as a model product due of their broad availability. 52 pharmaceutical businesses worldwide provided sixty-four paracetamol medicine samples for purchase. NIR, MIR, and NMR spectroscopy were utilized to create three data sets from 56 tablet-formulated formulations. Due to the high paracetamol content, the samples' MIR and NIR spectra (as shown in Figures 5 and 6) were highly comparable. Paracetamol Polfa Lodz (62% w/w) (marked 41) and Panadol Acti Fast (38% w/w) (marked 59) were the only exceptional cases, as was expected. Their distinct compositions, which include an extra 170 mg of sorbitol and 630 mg of sodium

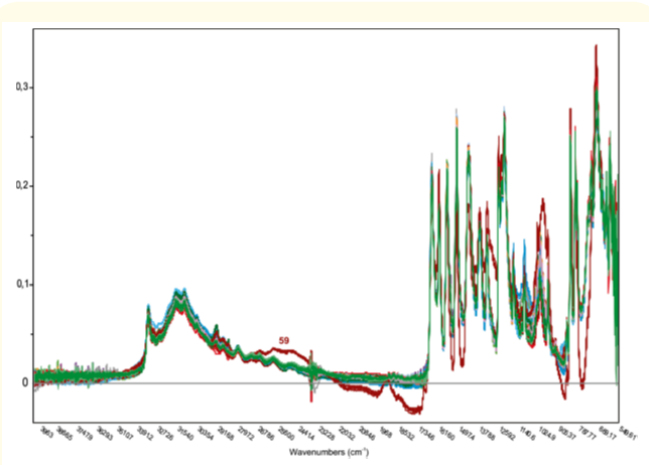

Figure 5: MIR spectra of paracetamol samples studied.

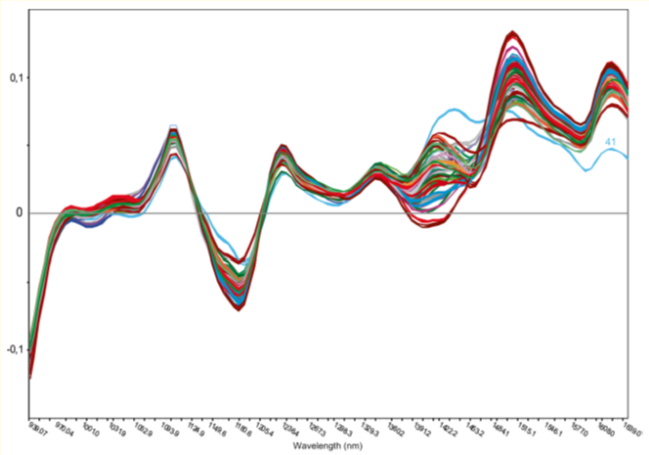

Figure 6: NIR spectra of paracetamol samples.

hydroxycarbonate, respectively, account for the notable differences in their spectra.

A crucial aspect of complementary health practices is the prescription of traditional Chinese medicine (TCM), with its complex formulas and subtle ingredients. The quality and safety of these therapeutic products are seriously threatened by the rise in herb adulteration brought on by the growth of the TCM market. One example is the extensively used herb Lonicerae Japonicae Flos (LJF), which has been contaminated by the less expensive Lonicerae Flos (LF), hence reducing its therapeutic efficacy. To provide a portable, real-time solution for the quick and precise identification and quantification of adulterants in TCM, a technique combining chemometrics and hand-held NIR spectroscopy has been devised [42]. A spectrum database was created that provides comprehensive insights into the relationship between spectral features and sample compositions by gathering NIR spectra from LJF, LF, and adulterated samples (AS). Consequently, a classification model was able to identify adulterants with a cross-validation accuracy of 99.58%, reaching 100% for the test set. Samples with varying adulteration ratios were classified and subjected to additional spectral similarity analysis. The test set accuracy was 99.20%, and the cross-validation accuracy under the ideal model was 98.38%. Additionally, the study quantifies different levels of adulteration using 20 standard contaminated samples within a 0–100% adulteration gradient.

Figure 7 shows the characteristic FTIR PAS (photoacoustic spectroscopy) and DRIFT (diffuse reflectance) spectra of 5 different herbals: chamomile (A), silver birch (B), hibiscus(C), peppermint(D), and cornflower €. The examined herbal medicines' FTIR spectra exhibit organic materials and bonds in the sample in two spectral areas (850–1850 cm^{-1} and 2700–3200 cm^{-1}).

The ability to distinguish between various herbal medicine components (flowers, leaves, and stems) was then the next area of interest. This is an important part of the production and quality control of herbal medicines because production guidelines might not always be able to specify the ratio of flowers to leaves in dried HM.

In recent years, herbal remedies have become more popular as complementary therapies, even in Indonesia. To accelerate their effects, herbal treatments may unlawfully include synthetic pharmaceutical substances. The identification of synthetic pharmaceuticals in contaminated herbal items is critical due to the negative consequences of both short-term and long-term consumption. Adulterants such as sildenafil, phenylbutazone,

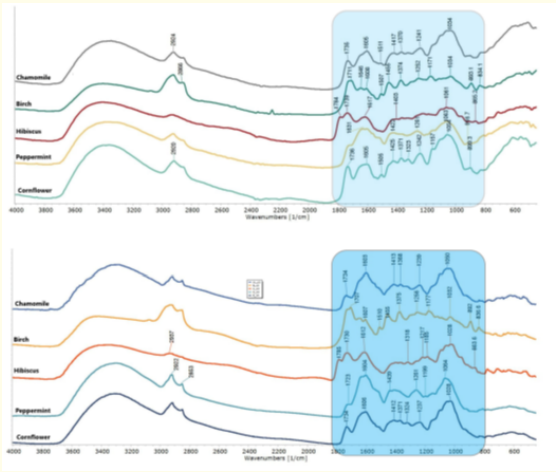

Figure 7: FTIR PAS spectra (A) and FTIR DRIFT spectra (B) of herbal medicines: chamomile (*Matricaria recutita*), silver birch (Betulapendula Roth), hibiscus (*Hibiscus sabdariffa*), peppermint (*Mentha piperita*) and cornflower (*Centaurea cyanus*). The fingerprint region 800–850 cm^{-1} is colored in blue.

and sibutramine HCl are frequently detected in Indonesian herbal remedies meant to increase sexual desire and performance, ease muscle soreness, and help people lose weight. In a study, ATR-FTIR spectroscopy was used in conjunction with chemometrics to quickly and economically detect sildenafil citrate, phenylbutazone, and sibutramine in Indonesian herbal items and herbal medicine formulations [43].

Figure 8a presents the reference infrared spectrum of sildenafil citrate. The standard sildenafil citrate spectrum shows significant absorption peaks at 1698 cm^{-1} (carbonyl group (C=O stretch)), 1579 cm^{-1}, and 1489 cm^{-1} (aromatic C=C bonds of the benzene ring); saturated C-H strain at 2874 cm^{-1}, unsaturated C-H strain at 3028 cm^{-1}, and secondary N-H strain at 3294 cm^{-1}. The aromatic C-H out-of-plane deformation occurred at 939 cm^{-1}, which resulted in the addition of new peaks at 1171, 784, 691, and 587 cm^{-1} [44,45].

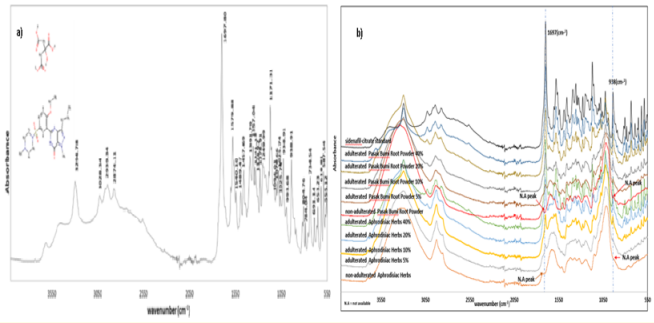

Figure 8: ATR-FTIR spectra.

a) Sildenafil citrate reference spectrum

b) Adulterated and non-adulterated pasak Bumi (E. longifolia Jack.) root powder and aphrodisiac herbs samples.

Sildenafil, phenylbutazone, and sibutramine adulteration in herbal powder and materials used as aphrodisiacs, analgesics, and slimming agents, respectively, can be detected using the proposed method. The study recommends employing FTIR spectrum data for rapid screening for synthetic adulterants in natural herbs and plant medicine items.

The ATR-FTIR spectra of eleven samples of both adulterated and non-adulterated aphrodisiac herbs, along with powdered Pasak Bumi (*E. longifolia* Jack.), are displayed in Figure 8b. Strong absorption in 1697 cm^{-1}, believed to be characteristic of the carbonyl group (C=O stretching), was not present in the absorption spectra of unadulterated samples of aphrodisiac herbs and powdered Pasak Bumi root. There were also peaks around 938 cm-1. There were also no peaks around 938 cm^{-1}. Peaks at 1697 and 938 cm^{-1}, which were lacking in the spectra of samples of aphrodisiac herbs and unadulterated Pasak Bumi root powder, clearly indicate the presence of sildenafil citrate.

Expired formulations, inexpensive medicines whose active ingredients and excipients are either completely or partially substituted with similar compounds, and products stored in inappropriate settings are all examples of contaminated pharmaceuticals. These items cause almost a million fatalities a year, making them the most serious threat to global health [13]. Recently, repackaging expired medications-a type of counterfeiting-has grown common, particularly in developing nations [15].

One crucial element in identifying contaminated medications is container authentication. Since any part of a medication can be tampered with, suspect samples must undergo both chemical and packaging checks [46].

Only a small number of publications about the examination of suspected items' packaging are published, even though many papers on drug authentication are mentioned. Infrared Attenuated Total Reflection (ATR), Raman, and XRF (X-ray fluorescence) spectroscopy have been used to examine the quality of the cardboard of the boxes, the paper of the leaflets, and the printing ink [47,48].

The polymer/plastic packing material from both real and fake products was chopped into tiny pieces and put in the middle of the FTIR's diamond crystal surface [48]. To identify the components of counterfeiting, the spectra obtained for the genuine and suspected counterfeit packaging materials were examined and contrasted. DSC was used to further examine the medicinal items, both authentic and counterfeit.

The ATR-FTIR spectra of the counterfeit (A1, B1, and C1) plastic blister samples and the authentic plastic blister samples (A, B, and C) displayed very similar characteristics, as can be seen in Figure 9. If a polymer with the same chemical constituent is employed in the packing materials, ATR-FTIR's capacity to characterize the polymer utilized to distinguish between genuine and fake samples exhibits certain limits. By distinguishing the melting points of the polymers in the two samples, DSC proved its capacity to swiftly identify counterfeit goods. Despite having comparable FTIR spectra, DSC enabled us to differentiate between various PVC qualities based on their thermal transitions.

Conclusions

Infrared spectroscopy in green analytical chemistry did not require sample pretreatment. Adulterated and unadulterated analgesic drugs, including synthetic or herbal medicines, might be distinguished utilizing qualitative analysis employing PCA and DA. Additionally, based on the statistical parameter value, the multivariate calibration analysis performance produced an ideal outcome. For pharmaceutical product quality control, FTIR-ATR in conjunction with different chemometric methods successfully provided a viable approach that is valid, efficient, effective, and reliable, particularly for screening drug adulterants in chemical and herbal products.

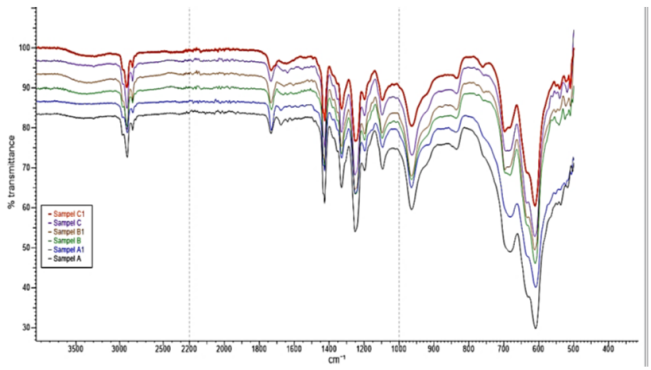

Figure 9: ATR-FTIR spectra of blister packaging for samples A, A1, B, B1, C, and C1.

Several international agencies, including the WHO, UNODC (United Nations Office on Drugs and Crime), INTERPOL, and WCO (World Customs Organization), are involved in the fight against fake and counterfeit medications. Studies have demonstrated the effectiveness of international operations such as the WCO's STOP programs and INTERPOL's Operation Pangea in disrupting criminal networks and seizing counterfeit medications [49-52]. However, financial issues and the difficulties of integrating their roles and responsibilities have presented challenges for these organizations. The UNODC has made recent endeavors to promote international collaboration in combating falsified and counterfeit medicines. One suggestion involves establishing a tri-lateral coalition comprising the WHO, UNODC, and INTERPOL [53].

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