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Integration of Analytical Techniques (HPLC & FTIR) for Enhanced Quality Assurance in Drug Formulation

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Abstract: *The pharmaceutical industry is expected to adhere to strict quality control (QC) standards to ensure that its herbal medicinal preparations remain consistent, safe, and effective. High-Performance Liquid Chromatography (HPLC) and Fourier Transform Infrared (FTIR) spectroscopy are two examples of such technologies that are used frequently due to their dependability and complementary analytical capability. While fast, non-destructive analysis based on molecular and functional group determination is offered by FTIR, HPLC provides great sensitivity, selectivity, and accuracy in the quantitative detection of active medicinal ingredients and impurity profiling. The principles, applications, and benefits of combining HPLC with FTIR to improve the quality of pharmaceuticals are reviewed in this paper. It is stressed that they are used together to check the quality of raw materials, in-process quality control, stability and shelf-life testing, and identify the formulation discrepancies and batch-to-batch differences. The topicality of this combined solution in the regulatory compliance, the quality risk management and the development of the analytical methods is also described. Moreover, new developments in green analytical chemistry and process analytical technology are emphasized, which points to the opportunities of HPLC-FTIR integration as the way of enhancing efficiency and sustainability in the quality control laboratories*

Keywords: Pharmaceutical, Drug discovery, Chemistry, Spectroscopy, Chromatography, HPLC & FTIR

I. INTRODUCTION

The World Health Organisation (WHO) is very concerned about the quality control of pharmaceutical drugs. The lack of assurance that these products of adequate quality, safety, and efficacy puts health services at danger. As long as the product is kept in its original, unopened container and according to the FDA's guidelines, it should remain effective and safe for consumption for the whole duration of its shelf life [1]. That is why pharmaceutical quality and stability management are major concerns [2]. The production process, including proper packing and formulation, is intricately related to the quality of pharmaceutical products, which is in turn affected by storage conditions and the passage of time. Pharmaceutical active ingredients (APIs) are crucially protected against environmental hazards including oxygen and light exposure, humidity, and temperature by excipients and tablet coatings.

Reagent-free UV-spectrophotometry is an environmentally friendly analytical method since it uses little energy, doesn't damage samples, produces little waste, and requires less expensive instruments. Its versatility and ease of use make it a popular choice for low-budget QC testing facilities that deal with a variety of UV-absorbing analytes [3]. However, due to its low selectivity, it is frequently supplemented or substituted by more expensive but more efficient separation methods, including HPLC [4], which solves the problem of analysing multicomponent mixtures. Although HPLC is an effective method for separating complex materials, it is also a big source of organic solvent waste and higher energy consumption in quality control laboratories. Reduced reliance on harmful solvents in conjunction with smaller LC instruments, such as capillary columns and nanoscale systems, allows for a more environmentally friendly form of liquid chromatography.

One of the most used approaches to understanding chemical structures is the Fourier transform infrared spectra (FTIR)

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technique, especially when combined with pattern recognition software. To diagnose the impacts of storage on the quality control of traded saffron, the most valuable chemical components were determined using FT-MIR coupled to principal component analysis [5]. Aside from this, other methods like HPTLC, UPLC-QTOFMS, and gas chromatography combined with mass spectrometry (GC-MS) have showed promise when applied to herbal remedies.

A. Structure of the Paper

This paper is organized as follows: Section II overview of Pharmaceutical Quality Assurance. Section III discusses concept of HPLC and FTIR. Section IV presents applications in drug formulation quality assurance. The literature are reviewed in Section V. while Section VI Conclude and future work of this study.

II. PHARMACEUTICAL QUALITY ASSURANCE FRAMEWORK

Quality control and assurance in the pharmaceutical sector are greatly supported by pharmaceutical analysis. Analytical chemistry comprises quantitative and qualitative assessments of raw materials, and it backs: Finding new drugs (by analysing structures, checking for purity, and profiling impurities) Developing, testing, and optimising formulations, APIs, intermediates, and final products to guarantee their safety, efficacy, and identity. investigations, bioequivalence/bioavailability tests, production (in-process controls, release testing) following the sale (checking quality, batch uniformity) [6]. Advances in equipment (UV-Vis spectroscopy, HPLC, GC, MS, FTIR, NMR) have enhanced accuracy, speed, and cost-effectiveness. Modern analysis also takes into account bioanalytical measures for pharmacokinetics, toxicokinetic, and therapeutic drug monitoring. Pharmaceutical analysis includes the identification, quantification, and measurement of pharmaceutical substances using a variety of analytical methods. identify, characterize, and quantify pharmaceutical compounds. These methods include:

- **Chromatography:** Gas chromatography, thin-layer chromatography, and high-performance liquid chromatography All three of these techniques.
- **Spectroscopy:** The term "spectroscopy" can refer to a wide variety of methods, some of which include fluorescent, infrared, and nuclear magnetic resonance (NMR) based.

A. Quality assurance in regulatory affairs of a pharmaceutical industry

A regulatory matter as, as stated in the title, the first thing that comes to mind when hear the word "regulatory" is laws and regulations. Here we'll go over the ways in which the regulatory affairs department and quality assurance operate together for the benefit of the pharmaceutical industry, namely how they both contribute to the industry's bottom line [7]. Because regulatory affairs is primarily concerned with the rules and regulations that govern the pharmaceutical sector and the products that fall within its purview, quality assurance paperwork is crucial for gaining approval for any matters in this area.

A regulatory affairs department's dossiers are crucial, as they are typically utilised for product registration in other nations. The most crucial parts of a drug dossier are the quality assurance data and the Certificate of Analysis (COA), but it is necessary to include information on the pharmaceuticals themselves in this dossier as well. Two Separate Dossiers.

- Common Technical Dossier (CTD)
- Asian Common Technical Dossier (ACTD)

Common Technical Dossier (CTD)

This is the standard format for the CTD, which is utilised for drug registration in nations that are not classified as Asian. Because drug quality is of utmost importance to all relevant agencies, CTD QA documentation is crucial. When a medicine is of excellent quality, it has a better probability of being registered in that nation. These generate substantial income for the sector.

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Asian Common Technical Dossier (ACTD)

The QA documentation is a crucial part of the standard format for drug dossiers used to register pharmaceuticals in Asian nations. If the drug has good quality, the chances of registration in Asian countries are high. Furthermore, the corporation benefits and generates a lot of money because its products are registered in other nations.

B. Principl*es of quality risk management*

Quality risk management is based on two main principles:

- Based on scientific understanding, the risk to quality evaluation should eventually lead to patient protection.
- The amount of risk should dictate the degree of formality, documentation, and effort put into a quality risk management process.

C. Risk management methods and tools

Commonly utilised, easy-to-understand methods for arranging data and streamlining decision-making in risk management include [8]:

- **Failure Mode Effects Analysis (FMEA):** Analysing the potential causes and consequences of process failures is possible with the help of Failure Modes and Effects Analysis (FMEA).
- **Failure Mode, Effects and Criticality Analysis (FMECA):** An FMECA might be created by expanding FMEA to include a study of the effects' severity, their likelihood of occurrence, and their detectability.
- **Fault Tree Analysis (FTA):** One approach is the FTA tool, which is based on the assumption that a product or process is flawed. Although it examines system or subsystem failures independently, this tool is able to aggregate numerous failure reasons by locating causal linkages.
- **Hazard Analysis and Critical Control Points (HACCP):** It is a systematic approach that uses technological and scientific principles to identify, analyse, and control risks associated with product lifecycle activities.
- **Preliminary Hazard Analysis (PHA):** PHA is a method for analysing potential dangers that could impair a certain activity, facility, product, or system in the future by drawing on prior knowledge or experiences with known hazards.
- **Risk Ranking and Filtering:** The purpose of risk rating and filtering is to compare and rank hazards. When evaluating complex systems for risk, it is common practice to use a wide range of quantitative and qualitative criteria. The risk ranking can be adjusted to match management or policy objectives with the help of "filters," which are weighting variables or cut-offs for risk scores.

D. Role of analytical method development

Analytical methods development plays a critical role in pharmaceutical analysis, including:

- **Method Development:** developing and optimizing analytical methods to detect and quantify pharmaceutical substances.
- **Method Validation:** validating analytical methods to ensure their accuracy, precision, and reliability.
- **Method Transfer:** move methods of analysis that have been validated to new laboratories or instruments.
- **Ensuring Product Quality:** Verifies accuracy of dosage, impurity and shelf-life stability.
- **Supporting Regulatory Compliance:** Provides data that meet ICH/FDA requirements for safety, efficacy, and quality.
- **Facilitating Drug Development:** Enables bioavailability studies, impurity profiling, and formulation testing.
- **Process Optimization:** Improves efficiency, reduces cost, and ensures robustness against small variations.

E. Appropriate dispensing and use

The method of dispensing improperly leads to the destruction and contamination of pharmaceutical products or medication errors. The succeeding processes are useful in ensuring that the pharmaceutical products are of standard quality:

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- Paper envelopes, which are commonly used for end-user dispensing, not protect tablets and capsules. Only use airtight containers, light-resistant bags, or vials for distributing [9].
- Ensure the dispensed medicines are clearly labeled and implement processes to label the products with the name of the patient, the name of the medicine, its strength, its expiry date as well as how to store and use it.
- Avoid using acronyms or symbols when writing instructions and information in the local language.

III. CONCEPT OF HPLC AND FTIR

HPLC is an advanced chromatography process to separate the pharmaceutical compounds in complex solutions and determine the compounds compositions and quantify them using this method [10]. The stationary phase operation in combination with the mobile phase high pressure allows HPLC to quantify API concentrations and trace impurities hence ensuring purity levels and regulatory compliance levels of drugs. The technology is used widely in stability testing and in bioequivalence testing and quality control to demonstrate that an intact medication survived during its dispersion phase (Figure 1).

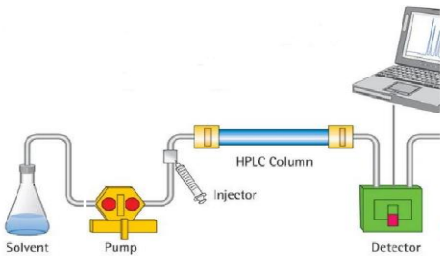

Fig. 1.High Performance Liquid Chromatography

A. Types of HPLC

The stationary phase and solvent types are two of several factors that allow for the categorisation of HPLC into different categories:

- **Normal-Phase HPLC:** In this mode, a non-polar mobile phase (like hexane) is mixed with a polar stationary phase (like silica). When separating polar substances, it works wonderfully.
- **Reverse-Phase HPLC (RP-HPLC):** This HPLC technique, which is the most used, uses a polar mobile phase (such water or methanol) and a non-polar stationary phase (like C18). Many different types of compounds, including medicines and biological substances, are best separated using RP-HPLC.
- **Size-Exclusion Chromatography (SEC):** SEC separates molecules based on their sizes. The stationary phase is made up of porous beads that smaller molecules can squeeze inside, causing them to move more slowly than bigger molecules.
- **Ion-Exchange Chromatography (IEC):** This technique employs a charged stationary phase and electrostatic forces between the analytes to separate charged species. Its primary application is in the synthesis of biomolecules, including proteins and nucleic acids.
- **Affinity Chromatography:** Biological activity is sacrificed in favour of selective separations achieved by specific interactions between analytes and ligands and the stationary phase in this form of chromatography.

B. Applications of HPLC

The ease of use of HPLC has seen its application in numerous industries and research markets. It can be used for many different purposes [11]:

- **Pharmaceutical Industry:** HPLC is a vital tool for pharmaceutical companies to ensure that their APIs and excipients are of the highest quality and concentration. Additionally, it is utilised in the process of drug development and stability testing.

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- **Biotechnology:** Biotechnology also makes use of high-performance liquid chromatography (HPLC) for the analysis and purification of biomolecules such as proteins, peptides, and nucleic acids. It allows researchers to carry out assays that identify enzyme activity or a particular biomolecular interaction.
- **Environmental Monitoring:** HPLC is very important in analysis of pollutants and toxins in the environment. Soil, water, and air contaminants such as pesticides and heavy metals can be located with its help.
- **Food and Beverage Industry:** HPLC is an essential tool for determining if food is safe to eat and of high quality. Flavour compounds, additives, pollutants, and nutritional values can all be studied using it. Additionally, methods for identifying food-borne diseases have been developed.
- **Clinical Applications:** HPLC finds its use in the medical field in both diagnosis and following therapeutic drugs in patients. Various analytes, including hormones and metabolites, can be extracted from urine and blood samples using this method [28].
- **Forensic Science:** HPLC is applied in toxic analysis, drug analysis, and metabolite analysis of biological samples, in forensic science and in the field of toxicology, as a contribution to criminal investigation and in toxicology studies.

C. Advantages of HPLC in Quantification

Several advantages characterise HPLC as a method for the quantitative analysis of medicinal substances:

- **High Sensitivity:** HPLC is able to identify and measure small amounts of pharmaceutical compounds, usually down to nanogram or even picogram quantities [12].
- **Specificity:** The method permits the component separation of intricate mixtures of substances, including isomers, metabolites and impurities and quantification of the components is correct.
- **Versatility:** The HPLC can be adapted to analyse a wide range of pharmaceutical compounds with diverse chemical properties by adjusting the mobile phase, stationary phase, and detection methods.
- **Speed:** Modern high-performance liquid chromatography (HPLC) systems, especially those that incorporate UHPLC, provide a high throughput due to the rapidity of the process.

D. Fourier Transform Infrared (FTIR) Spectroscopy

FTIR Spectroscopy detects the molecular features along with functional group composition of pharmaceutical compounds through infrared absorption pattern analysis. Infrared radiation causes particular sample molecules to vibrate in specific ways which produce unique spectral fingerprints for detecting drug-excipient interactions and incompatibilities [13]. The pharmaceutical industry heavily relies on FTIR for quality assessment and stability evaluation together with formulation development because this method reveals drug compositions while monitoring structural stability through time.

E. FTIR Spectroscopy Techniques

FTIR equipment has sparked the creation of numerous new sensitive methods for analysing substances that were previously unmanageable. The most popular Fourier transform infrared (FTIR) spectroscopy methods are photoacoustic spectroscopy (PAS) and attenuated total reflectance (ATR), as seen in Figure 2 [14]. The method, the light source, the detector, and the material being studied are all variables that affect the quality of the spectrum. Finding the right analysis method and tailoring it to each individual instance is, thus, of the utmost importance. The time needed to prepare samples has been drastically reduced thanks to the development of several FTIR techniques, making them an attractive option for laboratories and other real-world applications.

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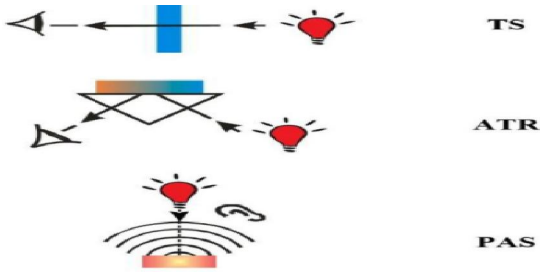

Fig. 2. Schematic representation of FTIR (TS, ATR and PAS)

Transmission Technique (TS)

The transmission technique (TS) is a widely used method in infrared spectroscopy. Excellent spectra with a respectable signal-to-noise (S/N) ratio and repeatability are provided by the TS method, making it a viable option for both qualitative and semi-quantitative analyses. Here, it's worth mentioning that the TS method doesn't actually quantify the amount of a material; instead, it gives an indicative reading of how much of a chemical was detected.

Attenuated Total Reflectance (ATR)

Internal reflection spectroscopy (IRS) is another name for the ATR method, which allows for the analysis of powders, soft solids, and other solid samples with flat, smooth surfaces, as well as liquids. Samples that absorb IR radiation significantly would not be amenable to analysis using the TS technique, yet this method is adaptable, non-destructive, highly sensitive, and widely applicable [15]. The absorption spectroscopy (ASTR) method measures the quantity of infrared light absorbed by a sample in the presence of a high refractive index (HRI) crystal, like a diamond, germanium, silicon, or zinc selenide. When infrared light is reflected internally multiple times by HRI material, it creates an evanescent wave. The evanescent wave weakens as it absorbs the sample at the sample/crystal interface.

Photoacoustic FTIR Spectroscopy (PAS)

Photoacoustic spectroscopy (PAS) is a method that uses sound waves to detect the absorption of light. The principle behind it is the photoacoustic effect, which occurs when a material absorbs modulated electromagnetic radiation and then produces an acoustic wave at its surface. The depth of sampling depends on the wavenumber of the infrared and the wavenumber decreases as the wavenumber increases. As with ATR, the sampling depth in PAS depends on the wavenumber as well [16]. Traditional photoacoustic spectroscopy involves immersing the sample in a gas (often helium) within a sealed cylinder (the photoacoustic cell). In this setup, a photoacoustic cell is coupled with a sensitive microphone that picks up the signal produced when a modulated radiation source is pointed at the surface of the sample.

F. FTIR Applications in Inorganic Materials Based on Their Fundamental Classification

The chemical make-up, bonding types, and structural characteristics of inorganic materials allow for multiple classifications. The post went over how some of these basic types can be studied using Fourier transform infrared spectroscopy [17].

Oxides

Oxide compounds consist of oxygen combined with another element, typically a metal. Using Fourier transform infrared spectroscopy to examine both basic oxides (such as SiO2, TiO2, and Al2O3) and complicated mixed oxides (such perovskites and spinels). Oxides' FTIR spectra are primarily characterised by metal-oxygen stretching and bending vibrations.

Carbonates and Bicarbonates

Carbon cycles and environmental processes are affected by the large amounts of calcite (CaCO3), dolomite, and CaMg (CO3)2 that are found in sedimentary rocks (Figure 3). Their actions provide light on the processes of carbon sequestration, carbonate reservoir formation, and geological history prediction. To differentiate carbonate minerals,

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FTIR analyses the various absorption bands of the carbonate ion (CO32−).

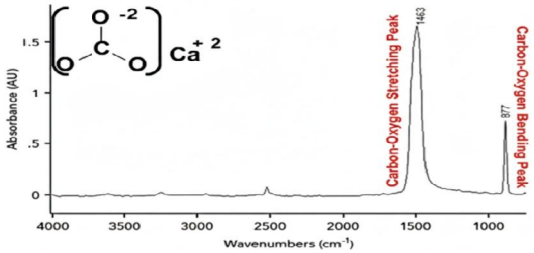

Fig. 3.FTIR spectrum of CaCO3

Phosphates

The majority of phosphate materials, such as apatite (Ca5(PO4)3(OH)), contain PO43− groups. Figure. 4 shows that their detection wavelength is 400-600 cm−1, which corresponds to P-O bending vibrations. The range of wavelengths for P-O asymmetric stretching is 1000-1200 cm−1. The stretching of the P-O bond is between 900 and 950 cm−1.

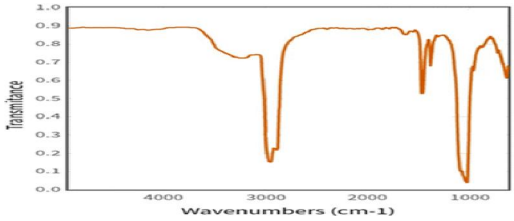

Fig. 4.FTIR spectra of calcium phosphate, tribasic

1) *Hydrotalcite*

The anionic clay family includes compounds similar to hydrotalcite, such as layered double hydroxides (LDH). An way to uncover the structures of LDH and intercalated anions between LDH layers is the Fourier transform infrared spectroscopy method [18]. A significant absorption band at 3480 cm−1 and a shoulder band at 3000 cm−1 were observed in the LDH FTIR spectra, which were linked to the stretching vibration of the OH groups.

2) Perchlorates and chlorates

The distinct Cl-O stretching bands observed in FTIR spectrums of perchlorate (ClO4−) and chlorate (ClO3−) ions make them easy to detect and distinguish. It is usual for perchlorates to have noticeable bands between 1100 and 1000 cm−1, while chlorates are more frequently observed in the range of 950 to 1000 cm−1. A small shift in the relative positions of these bands is possible for different cation and hydration levels.

IV. APPLICATIONS IN DRUG FORMULATION QUALITY ASSURANCE

Combination of chromatography-spectroscopy has greatly reinforced quality assurance measures in pharmaceutical formulation. Using a combination of the HPLC and FTIR, the quantitative and qualitative properties of the drug product can be measured in a holistic and trustworthy fashion. Raw Material Checking and Identity Testing [19].

A. Raw Material Verification and Identity Testing

This is accomplished through the joint use of HPLC and FTIR that provides a substantial framework of analysis. Specifically, quantitatively HPLC has the capability of determining prescription pharmaceutical substances (APIs) as well as the presence of impurities or adulterants at pharmacopeial standards. FTIR offers rapid qualitative analysis in the form of characteristic spectral fingerprints of chemical functional groups as an alternative. Together with one another, these approaches could lead to better credibility on the authenticity of the raw material and reduce the risk of using counterfeited inputs and contribute to the quality of the formulation consistency.

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B. In-Process Quality Monitoring

The key formulation parameters can be tracked in stages or real-time with the combination of HPLC and FTIR. The HPLC technique is particularly useful in the determination of the concentration of APIs, degradation products, and composition of intermediate products of such processes as blending, granulation and coating. This is supplemented with FTIR that provides real time non-destructive data on chemical integrity and potential interactions of APIs and excipients. Such a combination technique is very close to the principles of Process Analytical Technology (PAT), that enables the identification of the deviations early, and can assist in the timely correction of the situation in the production line.

C. Stability and Shelf-Life Test

Pharmaceutical quality assurance involves stability testing because it determines the shelf stability and storage of drug products. The joint HPLC and FTIR are employed to supply a general evaluation of the stability of chemicals and structure under the environment of accelerated and long-term storage [20]. HPLC has been extensively employed in the separation, identification, and quantification of degradation products that are formed as a result of thermal, photolytic or oxidative stress. Complementary information is provided by FTIR because it identifies the variations in the molecular bonding, polymorphic transitions, and variations in moisture. Combined, the methods allow a better insight into the degradation mechanisms and make the product shelf life prediction accurate.

D. Formulation Inconsistency and Batch-to-Batch Variation detection

Regulatory authority requires consistency between manufacturing batches and patient safety. The HPLC–FTIR analysis works well in detection of inconsistency in formulation as well as variation between batches [21]. HPLC allows the quantitative comparison of API content and profiles of impurities between batches, whereas FTIR allows assessment of the API quantitatively through spectral fingerprinting of formulation ingredients. Such a combined analytic approach reinforces quality management, lowers the potential of a product failure, and decreases the amount of expensive recall.

V. LITERATURE OF REVIEW

This section presents earlier studies on HPLC & FTIR for Quality Assurance in Drug. Table I provides a structured comparison of previous research, focusing on Techniques, Objective, Methods, Key Findings, Limitations and Future Work.

Cassserly, Burk and Acosta (2022) The parameters aren't in the right range, so upkeep needs to be done. Since there are established worldwide testing protocols, the inhibitor content of mineral insulating solutions is periodically checked. There aren't any universally accepted tests for ester liquids, mind. The group has come up with a dependable method that makes use of reversed-phase (C-18 column) HPLC along with an ultraviolet (UV) detector. The inhibitors can be isolated and quantified in the chromatogram using the acetonitrile elution procedure [22].

Markmann et al. (2022) An optical delay line that rotates can be used to achieve high spectral and temporal resolutions in Fourier transform infrared (FTIR) spectroscopy. The speed-spectral resolution trade-off observed in rapid-scan FTIRs can be mitigated with the utilisation of rotating motion and light sources like high-brightness quantum cascade laser frequency combs [23].

Wells (2022) Software quality assurance for recommender systems that aid in social decision-making is in its infancy, focussing on internal technological improvements; nonetheless, QA and QC are ubiquitous in other fields, like healthcare. Reliable quality assurance in addition to the "right to be an exception" provision for situations where data-driven recommendation system results can erroneously impose excessive restrictions on individual liberty [24].

Reno and Chowdhury (2021) generated and reviewed reports from pharmaceutical corporations' QA and QC departments using a private, permissioned blockchain built on Hyperledger. The assets of the blockchain record the results of the drug testing. As a result of the immutability of the assets created by transactions, the responsibility and transparency of the quality controlling management is preserved. Further, chaincode is utilised in the R&D phase of pharmaceutical processing to automate the system, ensure its safety, and safeguard the quality-assuring method from attacks that alter the data or penetrate its security [25].

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Abidin et al. (2021) Protein analysis and water-holding capacity were used to assess the differences. The stretching of carbon dioxide atoms in an O=C=O bond causes a spectral peak at around 2400 cm-1, which may be detected by FTIR spectroscopy and can be used to identify 5% beef liver in beef patties. More specifically, seven spots showed notable shifts as the percentage of cow liver in the patties rose: 3200 to 3600 cm-1, ~2925 cm-1, ~2855 cm-1, ~2400 cm-1, 1744 cm-1, 1650 cm-1, and ~1543 cm-1. The patties also varied greatly in terms of water-holding capacity and protein composition [26].

Mandalapu, Calzadilla and Mondesire (2020) method utilising artificial neural networks for feature categorisation has not been sufficiently tested for MS-HPLC. Researchers might be able to save time and effort by automating MS-HPLC feature classification if they find the best structure. Consequently, the best neural network architecture for MS-HPLC picture categorisation is found in this study. Automating HPLC-MS data analysis could be possible based on the results, which show a high level of accuracy (96.8%) [27].

Kumar et al. (2019) The plan is to use the unique properties of blockchain, such as its ability to handle sensitive information, to do a quantitative study on how to use these properties to permanently solve India's problem with fake drugs. Additionally, it strengthens the supply chain and brings much-needed transparency to transactions and quality assurance by tracking a drug from its raw material extraction all the way to the patient's body [28].

Table 1: Comparative Analysis of Quality Assurance and Analytical Frameworks in Pharmaceutical and Biomedical Domains

Authors	Technique	Objective	Methods	Key Findings	Limitations / Future Work
Cassserly, Burk & Acosta (2022)	HPLC Insulating Liquids QA	Development of a robust method to quantify inhibitors in ester insulating liquids	Reversed-phase HPLC using C-18 column with UV detector and acetonitrile elution	Successful separation and quantification of inhibitors despite lack of standardized ester test methods	Limited to laboratory-scale validation; lacks international standardization and long-term field validation
Markmann et al. (2022)	FTIR Spectroscopy	Improve time–frequency resolution trade-off in FTIR spectroscopy	Rotational optical delay line with quantum cascade laser frequency combs	Achieves high temporal and spectral resolution simultaneously	High system complexity and cost; limited discussion on industrial or routine QA implementation
Wells (2022)	Software Quality Assurance	Highlight the need for mature QA frameworks in recommender systems	Conceptual and ethical analysis of QA in decision-support systems	Emphasizes the necessity of accountability and user rights in automated decisions	Lacks experimental validation and domain-specific QA metrics; future work needed on formal QA frameworks
Reno & Chowdhury (2021)	Blockchain-based QA/QC	Ensure transparency and immutability in drug manufacturing QA/QC	Hyperledger private blockchain with chaincode automation	Secure, tamper-proof storage of QA/QC reports and R&D automation	Scalability, interoperability, and real-time integration with analytical instruments remain open challenges
Abidin et al. (2021)	FTIR – Food Quality Analysis	Detect beef liver adulteration in beef patties	FTIR spectroscopy with protein and water-holding capacity analysis	Detection possible at 5% adulteration; significant spectral and compositional differences	Focused on a single food product; requires validation across broader adulteration types and

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				observed	concentrations
Mandalapu, Calzadilla & Mondesire (2020)	AI + MS-HPLC	Automate feature classification in MS-HPLC data	Artificial Neural Networks for chromatogram image classification	Achieved 96.8% classification accuracy	Model generalizability and robustness across different instruments and datasets need further evaluation
Kumar et al. (2019)	Blockchain – Pharmaceutical QA	Eliminate counterfeit drugs in India through supply-chain transparency	Blockchain-based lifecycle tracking of drugs	Enhances authenticity, accountability, and traceability	Adoption barriers, regulatory alignment, and integration with legacy systems require further study

A. Deep Analysis on Literature Review

The literature indicates the rising trend of applying advanced analytical methods like HPLC and FTIR with intelligent and secure technologies in order to assure quality. HPLC and FTIR have proven to be capable of strong quantitative and qualitative analysis of the pharmaceuticals, food authentication and in insulating liquids, where the less stringent methods have been used. Recent trends also show that artificial intelligence to auto-interpret data and blockchain to provide transparency, traceability, and data integrity are observed. All in all, the research demonstrates the trend towards automated, reliable, and technology-based quality assurance models.

VI. CONCLUSION AND FUTURE WORK

Pharmaceutical medication formulation must comply to stringent quality assurance criteria to preserve patients' safety, therapeutic efficacy, and compliance with global standards. In that regard, the example of HPLC and FTIR spectroscopy becomes a potent and complementary analysis method in the entirety of pharmaceutical quality assessment objectives. These techniques are used in their synergistic combination, which allows quantitative determination of drug substances and structuring them qualitatively at the same time. Although HPLC has high sensitivity, specificity and reliability when quantifying API and also impurities fingerprinting but FTIR has a fast, non-destructive fingerprinting, which is applicable in identity testing, interaction studies and stability testing. Their combined use greatly improves raw material validation, in-process inspection, shelf life, and batch-to-batch consistency checks, which in turn aids regulatory compliance and decreases the likelihood of product failure.

The focus of future studies must be on the implementation of green and more environmentally friendly analytical methods such as solvent-reduction methods, small-scale chromatographic systems, and energy-efficient solutions. Automated decision-making, real-time quality control, and predictive stability modelling of Process Analytical Technology (PAT) systems can be achieved by the integration of chemometric data, AI, and ML with HPLC-FTIR data. In addition, the applicability and implications on industries will be increased by extending this integrated analytical method to complex formulations, continuous manufacturing systems, and biopharmaceutical products. Altogether, the further development of the interactive chromatography-spectroscopic techniques will be important to overpower pharmaceutical quality control in the contemporary drug production and development.

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