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A REVIEW OF THE ROLE OF FTIR, NMR, AND RAMAN SPECTROSCOPY IN DRUG PRODUCT CHARACTERISATION

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ABSTRACT

Drug product characterisation is a critical aspect of pharmaceutical development, ensuring the quality, safety, and efficacy of finished dosage forms. Spectroscopic techniques play a vital role in this process by providing rapid, reliable, and non-destructive analysis of drug substances and formulations. Among these, Fourier Transform Infrared (FTIR), Nuclear Magnetic Resonance (NMR), and Raman spectroscopy are widely employed due to their complementary analytical capabilities. FTIR is primarily used for functional group identification and compatibility studies, while NMR offers detailed structural elucidation and impurity profiling at the molecular level. Raman spectroscopy, with its minimal interference from water and suitability for in situ analysis, is particularly useful for polymorphic characterisation and real-time monitoring. These techniques collectively support critical applications such as structural confirmation, detection of degradation products, polymorphism analysis, and drug–excipient interaction studies. Their combined use enhances analytical accuracy and provides comprehensive insight into pharmaceutical systems. With ongoing advancements in instrumentation, chemometrics, and process analytical technology, spectroscopic methods are expected to play an increasingly significant role in modern pharmaceutical analysis and quality control.

INTRODUCTION

Drug product characterisation refers to the comprehensive evaluation of the physical, chemical, and structural properties of a pharmaceutical dosage form to ensure its identity, purity, potency, and overall performance. It involves the application of various analytical techniques to understand the composition of the drug product, including the active pharmaceutical ingredient (API) and excipients, as well as their interactions within the formulation. This process is essential throughout the drug development lifecycle, from Preformulation studies to final product release and stability testing. The importance of drug product characterisation lies in its direct impact on ensuring the quality, safety, and efficacy of pharmaceutical products. Accurate characterisation helps in identifying impurities, degradation products, and potential incompatibilities that may affect therapeutic performance or lead to adverse effects. It also supports batch-to-batch consistency and ensures that the drug product meets predefined specifications. Inadequate characterisation can result in compromised product quality, regulatory non-compliance, and potential risks to patient health [1,2].

Regulatory agencies emphasise the necessity of robust analytical characterisation in pharmaceutical development. Guidelines such as ICH Q2 (Validation of Analytical Procedures) and ICH Q6A (Specifications: Test Procedures and Acceptance Criteria for New

Drug Substances and Products) provide a framework for method validation, ensuring accuracy, precision, specificity, and reproducibility of analytical techniques. Stability guidelines (ICH Q1 series) further require characterisation of degradation behaviour under various stress conditions, reinforcing the need for reliable analytical tools capable of detecting subtle changes in drug products over time [3,4]. In this context, there is an increasing demand for rapid, non-destructive, and highly reliable analytical techniques that can provide detailed molecular and structural information with minimal sample preparation. Traditional methods, while effective, may be time-consuming and require extensive sample handling, which can introduce variability. Spectroscopic techniques have emerged as powerful alternatives due to their ability to deliver quick and accurate results while preserving the integrity of the sample [5].

Among these, Fourier Transform Infrared (FTIR), Nuclear Magnetic Resonance (NMR), and Raman spectroscopy have gained significant prominence in pharmaceutical analysis. These techniques offer unique and complementary insights into molecular structure, functional group identification, and intermolecular interactions. FTIR is widely used for identifying functional groups and studying drug–excipient compatibility, NMR provides in-depth structural and quantitative information, and Raman spectroscopy enables non-destructive analysis with minimal interference from water, making it suitable for in-line and real-time applications. Together, these spectroscopic methods form a comprehensive analytical platform for drug product characterisation, supporting modern pharmaceutical development and quality assurance [6,7].

FUNDAMENTALS OF SPECTROSCOPIC TECHNIQUES

Fourier Transform Infrared Spectroscopy (FTIR)

Fourier Transform Infrared (FTIR) spectroscopy is a widely used analytical technique in pharmaceutical sciences for the identification and characterisation of drug substances and formulations. It is based on the principle that molecules absorb infrared (IR) radiation at specific frequencies corresponding to the vibrational transitions of their chemical bonds. When IR radiation passes through a sample, certain wavelengths are absorbed, resulting in a spectrum that represents the molecular fingerprint of the compound [8].

FTIR is particularly valuable for functional group identification, as different chemical groups exhibit characteristic absorption bands in the infrared region. For instance, hydroxyl (–OH), carbonyl (C=O), and amine (–NH) groups can be easily identified based on their distinct peak positions. This makes FTIR an essential tool for confirming the identity of active pharmaceutical ingredients (APIs) and detecting potential interactions between drugs and excipients. Various sampling techniques are employed in FTIR analysis to accommodate different types of pharmaceutical samples. The most commonly used method is Attenuated Total Reflectance (ATR), which allows direct analysis of solids, liquids, and semi-solids with minimal sample preparation. Other methods include the KBr pellet technique, where the sample is mixed with potassium bromide and compressed into a transparent pellet, and transmission mode, which is suitable for thin films and solutions [9].FTIR offers several advantages, including rapid analysis, ease of operation, cost-effectiveness, and minimal sample preparation. It is a non-destructive technique, making it suitable for routine quality control and compatibility studies. However, FTIR has certain limitations, such as providing limited detailed structural information compared to techniques like NMR, and potential overlap of absorption bands, which may complicate the interpretation of complex mixtures [10].

Nuclear Magnetic Resonance (NMR) Spectroscopy

Nuclear Magnetic Resonance (NMR) spectroscopy is a powerful analytical technique widely used for detailed structural elucidation of pharmaceutical compounds. It is based on the principle that certain atomic nuclei, such as hydrogen (^{1}H) and carbon (^{13}C), possess spin and interact with an external magnetic field. When subjected to radiofrequency radiation, these nuclei absorb energy and transition between energy states, producing signals that can be translated into an NMR spectrum [11].

Key parameters in NMR spectroscopy include chemical shift, which provides information about the electronic environment of nuclei; coupling constant, which indicates interactions between neighbouring nuclei; and integration, which reflects the number of protons contributing to a signal. These parameters collectively enable precise determination of molecular structure and functional group connectivity [12].

Different types of NMR techniques are employed in pharmaceutical analysis. Proton NMR (^{1}H NMR) is commonly used for identifying hydrogen environments, while carbon-13 NMR (^{13}C NMR) provides information about the carbon skeleton. Advanced two-dimensional (2D) NMR techniques, such as COSY, HSQC, and HMBC, offer detailed insights into molecular connectivity and are especially useful for complex structures and impurity profiling.

NMR spectroscopy offers significant advantages, including comprehensive structural information, quantitative capability, and non-destructive analysis. However, it has limitations such as high instrumentation cost, requirement for specialised expertise, and relatively longer analysis time compared to other spectroscopic methods [13].

Raman Spectroscopy

Raman spectroscopy is an advanced vibrational spectroscopic technique used in pharmaceutical analysis for molecular characterization. It is based on the principle of inelastic scattering of monochromatic light, typically from a laser source. When light interacts with molecular vibrations, a small portion of the

scattered light undergoes a shift in energy, known as the Raman effect, which provides information about molecular structure[14].

Raman spectroscopy is considered complementary to FTIR, as it is particularly sensitive to non-polar bonds and symmetric vibrations that may be weak or inactive in infrared spectroscopy. This complementary nature enhances its utility in comprehensive drug characterisation [15].

One of the major advantages of Raman spectroscopy is its minimal interference from water, making it suitable for analyzing aqueous systems and biological samples. It is a non-destructive technique requiring little to no sample preparation and is highly suitable for in-line and real-time monitoring in pharmaceutical manufacturing, especially in Process Analytical Technology (PAT) applications. Despite its advantages, Raman spectroscopy has certain limitations. Fluorescence interference from some samples can obscure Raman signals, reducing sensitivity and accuracy. Additionally, the technique may require careful optimisation of experimental conditions to obtain reliable spectra [16].

APPLICATIONS IN DRUG PRODUCT CHARACTERISATION

Functional Group Identification

Spectroscopic techniques play a fundamental role in identifying functional groups present in drug molecules and formulations. FTIR spectroscopy is widely used for this purpose, as it provides characteristic absorption bands corresponding to specific functional groups such as hydroxyl, carbonyl, and amine groups. These spectral fingerprints enable rapid confirmation of the identity of active pharmaceutical ingredients (APIs) and excipients. Raman spectroscopy complements FTIR by effectively detecting non-polar bonds and symmetric vibrations that may be weak or inactive in infrared spectra. This makes Raman particularly useful in analysing compounds with low polarity. NMR spectroscopy further strengthens functional group identification by confirming the molecular framework and providing detailed information about the chemical environment of atoms, ensuring accurate structural verification [17,18].

Tab 01: Examples of functional group identification using FTIR, NMR, and Raman spectroscopy

Functional Group	Technique Used	Example Drug/Compound	Observation
–OH (Hydroxyl)	FTIR	Paracetamol	Broad peak 3200–3600 cm^{-1}
C=O (Carbonyl)	FTIR	Aspirin	Strong peak 1700 cm^{-1}
$–NH_2$ (Amine)	FTIR/NMR	Amoxicillin	N–H stretch 3300 cm^{-1}
C–H (Alkane)	FTIR	Ibuprofen	Peaks 2850–2960 cm^{-1}
Aromatic ring	Raman	Benzene derivatives	Strong Raman bands
C=C (Alkene)	FTIR	Atorvastatin	1600 cm^{-1}
Ether (C–O–C)	FTIR	Metformin	1100 cm^{-1}
Halogen (C–Cl)	Raman	Chloramphenicol	Fingerprint region
Amide group	NMR	Proteins/Peptides	Chemical shift (7–9 ppm)
Carboxylic acid	FTIR	Diclofenac	Broad + sharp peaks

Structural Elucidation

Structural elucidation is a critical step in pharmaceutical analysis, especially during drug development and impurity identification. NMR spectroscopy serves as the primary tool for determining molecular structure due to its ability to provide comprehensive information about atomic connectivity and spatial arrangement. Parameters such as chemical shift, coupling patterns, and signal integration allow precise identification of molecular architecture. Advanced two-dimensional (2D) NMR techniques, including COSY, HSQC, and HMBC, are particularly valuable for analysing complex molecules and resolving overlapping signals. In addition to NMR, FTIR and Raman spectroscopy provide supportive information by identifying functional groups and vibrational characteristics, thereby enhancing the reliability of structural interpretation when used in combination [19,20].

Tab 02: Examples of structural elucidation using spectroscopic techniques

Parameter	Technique	Example	Outcome
Chemical shift	NMR	Ethanol	Identifies CH_3, CH_2, OH
Coupling constant	NMR	Propanol	Neighbouring protons info
Integration	NMR	Acetone	Proton count
COSY	2D NMR	Complex drugs	Proton connectivity
HSQC	2D NMR	Alkaloids	C–H correlation
HMBC	2D NMR	Steroids	Long-range coupling
FTIR support	FTIR	Penicillin	Functional groups
Raman support	Raman	Lipids	Symmetric vibrations
Peak	NMR	Isopropan	Structural

splitting		ol	confirmation
Multiplicity	NMR	Aromatics	Substitution pattern

Detection of Impurities and Degradation Products

The detection and characterisation of impurities and degradation products are essential for ensuring drug safety and regulatory compliance. NMR spectroscopy is highly effective for impurity profiling and quantification, as it can detect and characterise minor components without the need for reference standards in some cases. FTIR spectroscopy aids in identifying degradation pathways by revealing changes in functional groups and chemical bonding patterns under stress conditions such as heat, light, or pH variations. Raman spectroscopy offers the advantage of real-time and in situ monitoring, making it suitable for tracking degradation processes during manufacturing and storage. Together, these techniques provide a comprehensive approach for identifying, monitoring, and controlling impurities and degradation products in pharmaceutical formulations [21].

Tab 3: Examples of impurity and degradation product detection using spectroscopy

Condition	Technique	Drug Example	Observation
Acid degradation	FTIR	Metformin	Peak shifts
Base degradation	NMR	Aspirin	New signals
Oxidation	Raman	Vitamin C	Structural change
Thermal stress	FTIR	Paracetamol	Degradation bands
Photolysis	Raman	Nifedipine	Color change spectra
Hydrolysis	NMR	Penicillin	Ring opening
Moisture effect	FTIR	Tablets	Broad peaks
Storage degradation	Raman	Insulin	Structural loss
Minor impurity	NMR	APIs	Low-level detection
Process impurity	FTIR	Bulk drugs	Unknown peaks

Polymorphism and Solid-State Characterisation

Polymorphism, the ability of a drug substance to exist in multiple crystalline forms, plays a crucial role in determining the physicochemical properties and performance of pharmaceutical products. Different polymorphs can exhibit variations in solubility, dissolution rate, stability, and bioavailability, ultimately influencing therapeutic efficacy. Therefore, accurate identification and control of polymorphic forms are essential during drug development and manufacturing. FTIR and Raman spectroscopy are widely employed for polymorph differentiation, as they provide distinct vibrational spectra corresponding to different crystal lattice arrangements. Subtle shifts in peak positions and intensities enable discrimination between polymorphic forms. In addition, solid-state NMR offers detailed insights into molecular packing and crystal structure, making it a powerful tool for comprehensive solid-state characterisation, particularly when other techniques provide ambiguous results [22,23].

Tab 04: Examples of polymorphism and solid-state characterisation of drugs

Parameter	Technique	Example Drug	Observation
Polymorph I vs II	FTIR	Carbamazepine	Peak variation
Crystal form	Raman	Ritonavir	Sharp peaks
Amorphous vs crystalline	NMR	Indomethacin	Broad vs sharp signals
Lattice vibration	Raman	Sulfathiazole	Fingerprint region
Molecular packing	Solid NMR	APIs	Structural insight
Hydrate vs anhydrate	FTIR	Ampicillin	Water peaks
Stability differences	Raman	Polymorph drugs	Peak shifts
Phase transition	FTIR	Theophylline	New peaks
Crystallinity index	Raman	Tablets	Intensity change
Solid dispersion	NMR	Formulations	Signal broadening

Drug–Excipient Compatibility Studies

Drug–excipient compatibility is a critical factor in formulation development, as interactions between active pharmaceutical ingredients (APIs) and excipients can affect stability, efficacy, and shelf life. FTIR spectroscopy is commonly used to detect such interactions by monitoring shifts, disappearance, or appearance of characteristic peaks, indicating possible chemical or physical incompatibilities. Raman spectroscopy complements FTIR by providing additional vibrational information, particularly for non-polar interactions, and can be used for rapid screening of formulations. NMR spectroscopy further enhances compatibility studies by offering molecular-level insights into interactions, such as hydrogen bonding or complex formation, which may not be easily detected by other techniques. Together, these methods provide

a robust approach for ensuring formulation stability and compatibility [24].

Tab 05: Examples of drug–excipient compatibility studies using spectroscopic methods

Interaction Type	Technique	Example	Observation
API + lactose	FTIR	Metformin	Peak shift
API + starch	Raman	Paracetamol	No interaction
API + Mg stearate	FTIR	Ibuprofen	New peaks
Hydrogen bonding	NMR	Polymer blends	Shift change
Complex formation	NMR	Cyclodextrin	Signal change
Physical incompatibility	Raman	Tablets	Intensity change
Moisture interaction	FTIR	Hygroscopic drugs	Broad peaks
Polymer interaction	NMR	Controlled release	Peak shift
Chemical degradation	FTIR	API mixtures	Disappearance
Stability study	Raman	Formulations	Real-time monitoring

Quantitative Analysis

Spectroscopic techniques are increasingly utilised for quantitative analysis in pharmaceutical applications. Quantitative NMR (qNMR) is a highly accurate and reliable method for absolute quantification of drug substances and impurities without the need for reference standards, based on the proportionality between signal intensity and the number of nuclei. FTIR and Raman spectroscopy can also be employed for quantitative purposes when combined with chemometric models, enabling the analysis of complex mixtures and formulations. These approaches are particularly valuable in Process Analytical Technology (PAT), where real-time monitoring and control of manufacturing processes are required. The integration of spectroscopic techniques into PAT frameworks enhances process understanding, ensures consistent product quality, and supports the implementation of continuous manufacturing strategies [25].

Tab 06: Examples of quantitative analysis using FTIR, NMR, and Raman spectroscopy

Method	Technique	Example	Application
qNMR	NMR	API assay	Absolute quantification
Calibration curve	FTIR	Tablets	Concentration
Chemometrics	Raman	Mixtures	Multicomponent analysis
Peak area	NMR	Impurities	Quantification
Beer's law	FTIR	Solutions	Linear response
PAT monitoring	Raman	Manufacturing	Real-time control
Standard-free analysis	NMR	Drugs	High accuracy
Multivariate analysis	Raman	Complex drugs	Data modeling
Inline monitoring	FTIR	Production	Continuous process
Content uniformity	NMR	Tablets	Dosage accuracy

Advantages and Limitations

FTIR spectroscopy is rapid, cost-effective, and requires minimal sample preparation, but provides limited structural detail. NMR spectroscopy offers comprehensive molecular and structural information with high accuracy, though it is expensive and time-consuming. Raman spectroscopy is non-destructive and suitable for real-time analysis with minimal preparation, but may suffer from fluorescence interference and sensitivity issues [26].

Tab 07: Advantages and Limitations of FTIR, NMR, and Raman Spectroscopic Techniques in Drug Product Characterization

Technique	Advantages	Limitations
FTIR	Rapid analysis; cost-effective; simple sample preparation	Limited structural detail; overlapping peaks
NMR	Detailed structural and molecular information; quantitative capability	Expensive instrumentation; longer analysis time
Raman	Non-destructive; minimal sample preparation; suitable for in-line analysis	Fluorescence interference; lower sensitivity in some cases

Complementary Role of FTIR, NMR, and Raman

FTIR, NMR, and Raman spectroscopy collectively provide a comprehensive analytical platform for drug product characterisation due to their complementary nature. FTIR and Raman spectroscopy primarily deliver vibrational information; FTIR is highly sensitive to polar functional groups, whereas Raman spectroscopy is more effective for non-polar bonds and symmetric vibrations. This complementary vibrational coverage

enables a broader understanding of molecular interactions within pharmaceutical systems.

NMR spectroscopy, in contrast, offers detailed structural insights, including molecular framework, atomic connectivity, and the chemical environment of nuclei. Parameters such as chemical shift, coupling constants, and signal integration allow precise structural confirmation. When used together, these techniques significantly enhance analytical accuracy, reproducibility, and confidence in results. Therefore, their combined application is considered essential for comprehensive and reliable pharmaceutical characterization [27].

REGULATORY AND INDUSTRIAL PERSPECTIVE

Spectroscopic techniques play a vital role in pharmaceutical quality control and quality assurance by enabling accurate identification, quantification, and monitoring of drug substances and products. Their use aligns with international regulatory requirements, particularly those outlined in International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines such as Q2 (validation of analytical procedures) and Q6A (specifications for new drug substances and products). Additionally, regulatory expectations from the U.S. Food and Drug Administration emphasise the need for validated, robust, and stability-indicating analytical methods. These techniques are extensively applied in stability studies to monitor degradation pathways and ensure product integrity throughout shelf life. Furthermore, their integration into Process Analytical Technology (PAT) frameworks enables real-time monitoring and control of manufacturing processes. This supports continuous manufacturing approaches, enhances process understanding, and ensures consistent product quality while maintaining regulatory compliance [28,29].

RECENT ADVANCES

Recent advancements in spectroscopic techniques have significantly enhanced their applicability in pharmaceutical analysis. The development of portable and handheld Raman instruments has enabled on-site and real-time analysis, improving efficiency in quality control processes. Advances in solid-state NMR have provided deeper insights into molecular structure and polymorphism. Furthermore, the integration of spectroscopic data with chemometrics and artificial intelligence has improved data interpretation and predictive capabilities. The emergence of hyphenated techniques and automation has further streamlined analytical workflows, increasing speed, accuracy, and reproducibility.

FUTURE PERSPECTIVES

The future of spectroscopic techniques in pharmaceutical analysis is focused on achieving faster, more efficient, and environmentally sustainable processes. Real-time release testing is expected to become more prevalent, reducing reliance on end-product testing and accelerating product release. Continuous manufacturing systems will increasingly adopt spectroscopic tools for process monitoring and control. Additionally, there is a growing emphasis on green analytical chemistry approaches that minimise solvent use and waste generation. The incorporation of advanced data analysis tools, including machine learning and artificial intelligence, will further enhance the capability of spectroscopic techniques to provide rapid and accurate insights into complex pharmaceutical systems.

CONCLUSION

In conclusion, FTIR, NMR, and Raman spectroscopy serve as powerful and complementary analytical tools in drug product characterisation, offering comprehensive insights into molecular structure, functional groups, and physicochemical properties. Their combined application enables accurate identification, impurity profiling, polymorphic analysis, and evaluation of drug–excipient interactions, thereby ensuring the quality, safety, and efficacy of pharmaceutical products. FTIR provides rapid functional group analysis, NMR delivers detailed structural and quantitative information, and Raman spectroscopy supports non-destructive and real-time monitoring. The integration of these techniques enhances analytical reliability and supports regulatory compliance with established guidelines. Furthermore, advancements in instrumentation, chemometrics, and process analytical technology have expanded their applications in continuous manufacturing and real-time quality control. As pharmaceutical industries move toward more efficient and sustainable practices, spectroscopic techniques will continue to play a crucial role in modern drug development and quality assurance systems

AUTHOR CONTRIBUTIONS

Kiran Kumar Byram: Conceptualisation, literature review, data curation, writing – original draft preparation, writing – review and editing, and final approval of the manuscript.

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