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Qualitative Characterization of Clozapine Tablet Samples

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ABSTRACT

The present study focuses on the qualitative characterization of Clozapine tablet samples with the aim of evaluating their physicochemical properties, identity, and quality attributes. Clozapine is an atypical antipsychotic drug widely used in the treatment of schizophrenia and other severe psychiatric disorders that are resistant to conventional therapy. Ensuring the quality, purity, and consistency of Clozapine tablets is essential for therapeutic efficacy and patient safety. In this investigation, different commercially available Clozapine tablet samples were subjected to various qualitative analytical tests to assess their organoleptic characteristics, physical appearance, color, odor, texture, and labeling compliance. Further characterization involved the determination of tablet dimensions, hardness, friability, disintegration time, and solubility behavior using standard pharmacopeial methods. Chemical identification tests were carried out to confirm the presence of Clozapine as the active pharmaceutical ingredient. Thin Layer Chromatography (TLC) and ultraviolet-visible (UV-Vis) spectroscopic techniques were employed for preliminary qualitative analysis and comparison among the samples. The results indicated that the tested formulations complied with acceptable pharmaceutical quality standards and showed comparable physicochemical characteristics. Minor variations observed among the samples may be attributed to differences in excipients, manufacturing processes, and storage conditions.

Keywords: Clozapine, Qualitative Characterization, Tablet Analysis, Pharmaceutical Quality Control, FTIR (Fourier Transform Infrared Spectroscopy)

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INTRODUCTION

Clozapine is one of the most effective atypical antipsychotic drugs used in the treatment of severe psychiatric disorders, particularly treatment-resistant schizophrenia. Since its introduction, Clozapine has gained significant importance in the field of psychopharmacology due to its superior efficacy in reducing both positive and negative symptoms of schizophrenia. It is also prescribed for patients who do not respond adequately to other antipsychotic medications. Despite its therapeutic advantages, Clozapine therapy requires careful monitoring because of potential adverse effects such as agranulocytosis, sedation, weight gain, and cardiovascular complications. Therefore, maintaining the quality, purity, and safety of Clozapine tablet formulations is essential for ensuring effective patient care.

Qualitative characterization of pharmaceutical tablet samples plays a crucial role in pharmaceutical analysis and quality assurance. It involves the identification and evaluation of the physical and chemical properties of a drug formulation to confirm its authenticity, composition, and compliance with pharmacopeial standards. In the case of Clozapine tablets, qualitative characterization helps determine the presence of the active pharmaceutical ingredient (API), excipients, color, odor, texture, solubility, and other organoleptic and physicochemical properties. Such studies are necessary to ensure that the marketed formulations meet the required standards of safety, efficacy, and stability.

The pharmaceutical industry follows strict guidelines established by regulatory authorities such as the World Health Organization (WHO), Food and Drug Administration (FDA), and Indian Pharmacopoeia (IP) to maintain the quality of medicinal products. Any variation in tablet composition, manufacturing process, or storage conditions may affect the therapeutic performance of the drug. Therefore, analytical evaluation and characterization of tablet samples are important

steps in drug quality control. Qualitative analysis also assists in detecting counterfeit or substandard products that may pose risks to patients.

Clozapine tablets are generally evaluated through various qualitative parameters including appearance, shape, size, color uniformity, hardness, friability, disintegration, and solubility characteristics. Advanced analytical techniques such as Fourier Transform Infrared Spectroscopy (FTIR), Thin Layer Chromatography and other identification methods may also be employed for confirming the identity and purity of the drug. These methods provide valuable information regarding the compatibility of the drug with excipients and help assess the integrity of the formulation.

The present study on "Qualitative Characterization of Clozapine Tablet Samples" aims to examine and evaluate the qualitative properties of different Clozapine tablet formulations available in the market. The study focuses on identifying the characteristics of the tablets and comparing them with standard pharmaceutical specifications. Through systematic evaluation, the research seeks to ensure the quality and reliability of Clozapine formulations used in clinical practice.

In conclusion, qualitative characterization is an essential aspect of pharmaceutical quality control that ensures the safety, effectiveness, and consistency of drug products. The evaluation of Clozapine tablet samples not only contributes to maintaining therapeutic standards but also supports regulatory compliance and patient safety. This study provides important insights into the pharmaceutical properties of Clozapine tablets and highlights the significance of analytical methods in modern drug evaluation and quality assurance.

Objectives of the Study

The major objectives of qualitative characterization of clozapine tablet samples are:

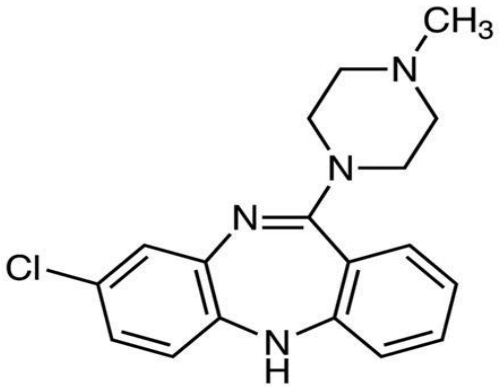
1. To identify the presence of clozapine in marketed tablet formulations.
2. To evaluate the compatibility of drug and excipients.
3. To compare different clozapine tablet samples with standard specifications.
4. To ensure quality, safety, and efficacy of pharmaceutical products.

Clozapine: Chemical and Pharmacological Profile

Clozapine is classified as a second-generation or atypical antipsychotic. It acts mainly by antagonizing dopamine D_2 receptors and serotonin 5-HT_2A receptors. The drug shows superior efficacy in managing both positive and negative symptoms of schizophrenia.

Chemical Properties

Property	Description
Chemical Name	8-Chloro-11-(4-methyl-1-piperazinyl)-5H-dibenzo[b,e][1,4]diazepine
Molecular Formula	$C_{18}H_{19}ClN_4$
Molecular Weight	326.83 g/mol
Appearance	Yellow crystalline powder
Solubility	Slightly soluble in water
Melting Point	Approximately 183–184°C



Structure of Clozapine

The physicochemical properties of clozapine influence its formulation behavior, dissolution, and stability.

Qualitative Characterization

Among the various analytical techniques used in pharmaceutical research, Fourier Transform Infrared Spectroscopy (FTIR) is one of the most important and widely applied methods for the qualitative characterization of drug substances and pharmaceutical formulations. FTIR is a rapid, accurate, non-destructive, and highly sensitive analytical technique used to identify functional groups, confirm molecular structure, and detect possible interactions between drugs and excipients. In the qualitative characterization of clozapine tablet samples, FTIR plays a vital role in ensuring the identity, purity, compatibility, and stability of the formulation.

Clozapine is an atypical antipsychotic drug chemically known as 8-chloro-11-(4-methyl-1-piperazinyl)-5H-dibenzo[b,e][1,4]diazepine. Because of its complex chemical structure and potent pharmacological activity, accurate identification of clozapine in tablet formulations is essential. FTIR spectroscopy helps in confirming the presence of clozapine by identifying its characteristic functional groups through specific absorption bands in the infrared region. Every chemical compound absorbs infrared radiation at unique frequencies corresponding to the vibration of chemical bonds present in the molecule. Therefore, the FTIR spectrum acts as a molecular fingerprint for the drug.

In FTIR analysis, infrared radiation is passed through the sample, and the absorbed frequencies are measured. The resulting spectrum represents the molecular vibrations of functional groups such as C–H, N–H, C=N, C–Cl, and aromatic ring structures present in clozapine. The obtained spectrum of the tablet sample is then compared with the spectrum of the pure standard drug. Matching peaks confirm the identity and authenticity of clozapine in the formulation.

The ATR (Attenuated Total Reflectance) method is commonly used in modern FTIR studies because it requires minimal sample preparation and provides rapid analysis. In ATR-FTIR, the tablet sample is directly placed on the crystal surface, and infrared light penetrates a short distance into the sample. This technique is especially useful in pharmaceutical analysis because it avoids complex preparation procedures such as pellet formation and reduces chances of sample contamination.
FTIR spectroscopy is particularly important in detecting drug–excipient interactions. Pharmaceutical tablets contain various excipients such as binders, lubricants, fillers, disintegrants, and stabilizers that support the manufacturing process and improve tablet performance. However, incompatibility between clozapine and excipients may lead to degradation, reduced potency, discoloration, or instability. FTIR helps identify such incompatibilities by observing changes in characteristic absorption peaks. Any disappearance, shifting, broadening, or appearance of new peaks in the spectrum may indicate chemical interaction between the drug and excipients.

For example, clozapine typically exhibits characteristic FTIR peaks corresponding to aromatic C–H stretching, C=N stretching, N–H bending, and C–Cl vibrations. If these peaks remain unchanged in the tablet formulation compared to the pure drug, it indicates compatibility between clozapine and excipients. On the other hand, major spectral changes may suggest instability or chemical reaction during formulation development.

Another important application of FTIR in qualitative characterization is the detection of counterfeit or substandard medicines. Counterfeit pharmaceutical products may contain incorrect ingredients or inadequate amounts of the active drug. FTIR spectroscopy provides a quick method for identifying whether the expected functional groups of clozapine are present in the tablet sample. Thus, the technique contributes significantly to pharmaceutical quality assurance and public health safety.

FTIR also plays an essential role in stability studies of clozapine formulations. Pharmaceutical products are sensitive to environmental conditions such as heat, moisture, oxygen, and light. These factors may cause chemical degradation during storage. FTIR analysis can detect structural changes in the drug molecule by monitoring alterations in absorption peaks over time. The technique therefore helps evaluate formulation stability and determine suitable storage conditions and shelf life.
In pharmaceutical industries and academic research laboratories, FTIR is preferred because of its numerous advantages. It is a rapid and non-destructive technique that requires only a small amount of sample. The method provides high sensitivity, reproducibility, and accuracy in identifying molecular structures. Additionally, FTIR instruments are computerized, allowing easy spectral interpretation, data storage, and comparison with reference libraries.

MATERIALS AND METHODS

The qualitative characterization of clozapine tablet samples requires various chemicals, reagents, instruments, and analytical techniques. The selection of appropriate materials and methods is essential to obtain reliable, reproducible, and accurate analytical results. Different physical and chemical tests are performed to evaluate the identity, compatibility, purity, and structural characteristics of the drug formulation.

Clozapine Tablet Samples
Marketed clozapine tablets from different pharmaceutical companies are collected for comparative evaluation. These samples help assess variations in formulation quality, appearance, and analytical characteristics among manufacturers.

Standard Clozapine Reference Sample
A pure standard sample of clozapine is used as a reference material for comparison during spectroscopic and chromatographic analyses. It serves as the authentic standard for confirming drug identity.

Fourier Transform Infrared Spectroscopy (FTIR)
FTIR analysis is one of the most important techniques used in qualitative characterization.

Principle
FTIR identifies functional groups by measuring absorption of infrared radiation at different wavelengths.

- The sample is mixed with potassium bromide.
- The mixture is compressed into a transparent pellet.
- The pellet is scanned in the IR region.

Characteristic Peaks of Clozapine

Functional Group	Absorption Peak (cm^{-1})
N-H stretching	3300–3400
Aromatic C-H stretching	3000–3100
C=N stretching	1600–1650
C-Cl stretching	700–800

Significance

- Confirms the presence of functional groups.
- Detects chemical degradation.
- Evaluates drug-excipient interactions.

FTIR spectra of tablet samples are compared with standard clozapine spectra for authentication.

Drug-Excipient Compatibility Studies
Excipients are inactive ingredients added to pharmaceutical formulations to improve processing, stability, appearance, and therapeutic performance. However, incompatibility between clozapine and excipients may lead to instability, degradation, or reduced efficacy.Therefore, compatibility studies are essential during formulation development.

Evaluation of Tablet Quality Parameters
Although qualitative characterization mainly focuses on identification and structural analysis, supportive physical quality tests are also performed to evaluate overall tablet quality.

FTIR Analysis
FTIR spectra were recorded using ATRtechnique within the range 4000–400 cm^{-1}.
Characteristic peaks observed:

Functional Group	Frequency (cm^{-1})
Aromatic C–H stretching	3050–3100
Aliphatic C–H stretching	2850–2950
C=N stretching	1590–1650
Aromatic C–Cl stretching	700–800

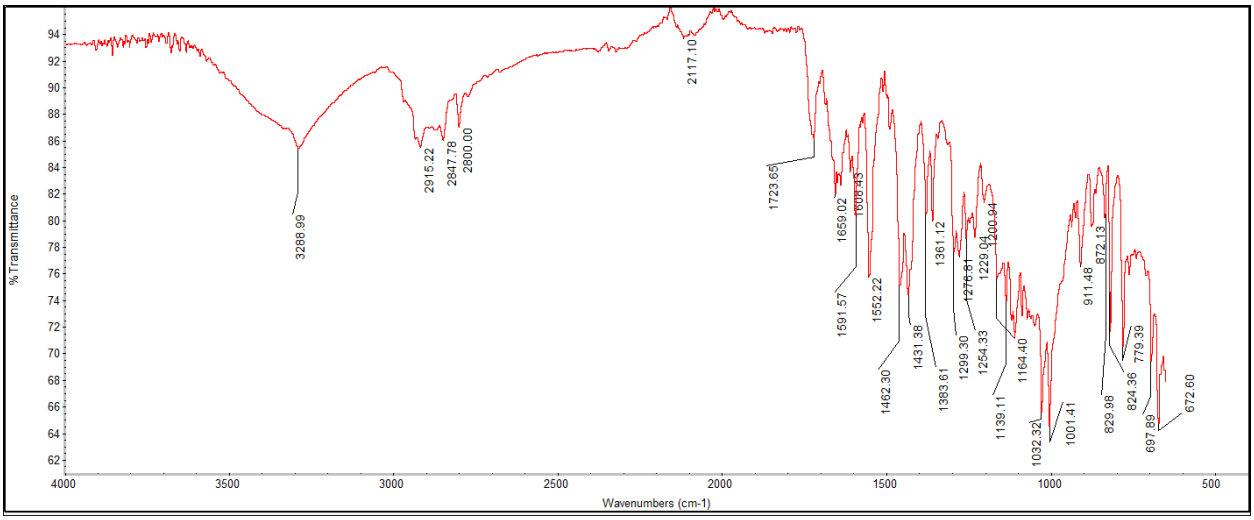
RESULTS AND DISCUSSION

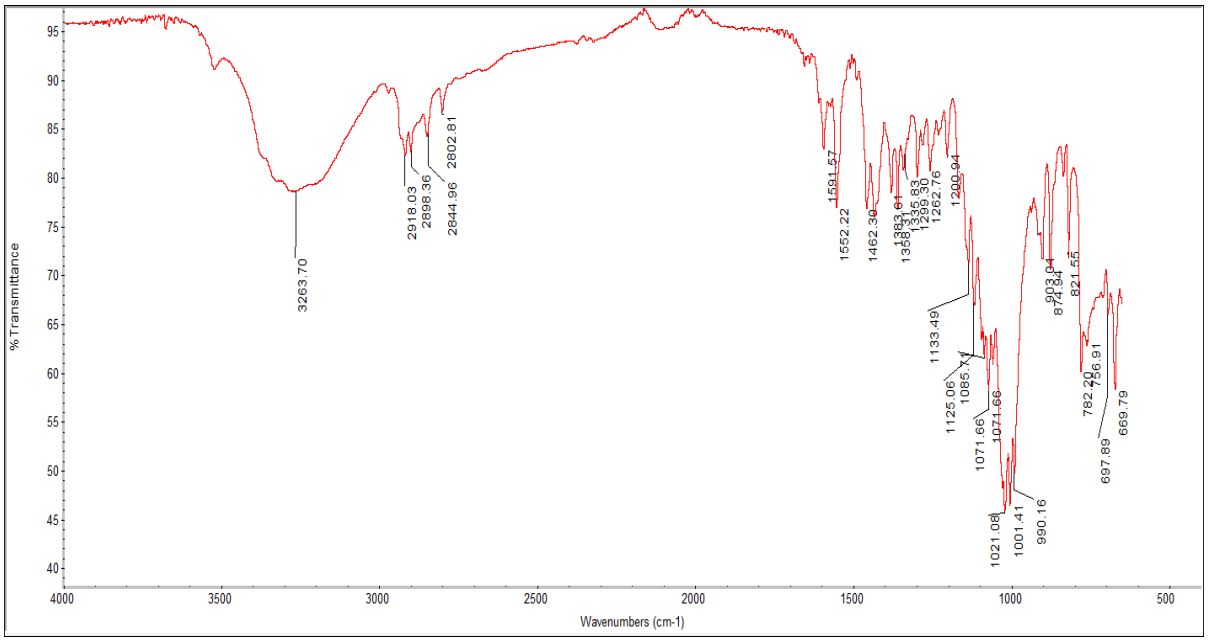
FTIR (Fourier Transform Infrared Spectroscopy) studies of marketed clozapine tablet samples confirmed the presence and structural integrity of the drug within the formulations. The FTIR spectra exhibited characteristic absorption peaks corresponding to the major functional groups present in clozapine. Prominent peaks were observed for aromatic C–H stretching, C=N stretching, C–N stretching, and other characteristic vibrations associated with the dibenzodiazepine

structure of clozapine. These peaks appeared at frequencies comparable to those reported for pure clozapine standard, thereby confirming the identity of the active pharmaceutical ingredient in the marketed tablet samples.

Furthermore, the spectra obtained from the formulated tablets did not show any significant shift, disappearance, or formation of additional peaks when compared with the pure drug spectrum. The absence of major spectral changes indicates that no significant chemical interaction or incompatibility occurred between clozapine and the excipients used in the tablet formulations. Minor variations in peak intensity were attributed to the presence of excipients and differences in concentration, which are commonly observed in formulated products.

The FTIR analysis also demonstrated that the characteristic functional groups of clozapine remained stable during formulation and manufacturing processes. The retention of all principal peaks suggests preservation of the molecular structure and chemical stability of the drug. Therefore, FTIR characterization confirmed the compatibility of clozapine with commonly used pharmaceutical excipients and supported the overall quality, identity, and stability of the marketed tablet formulations.





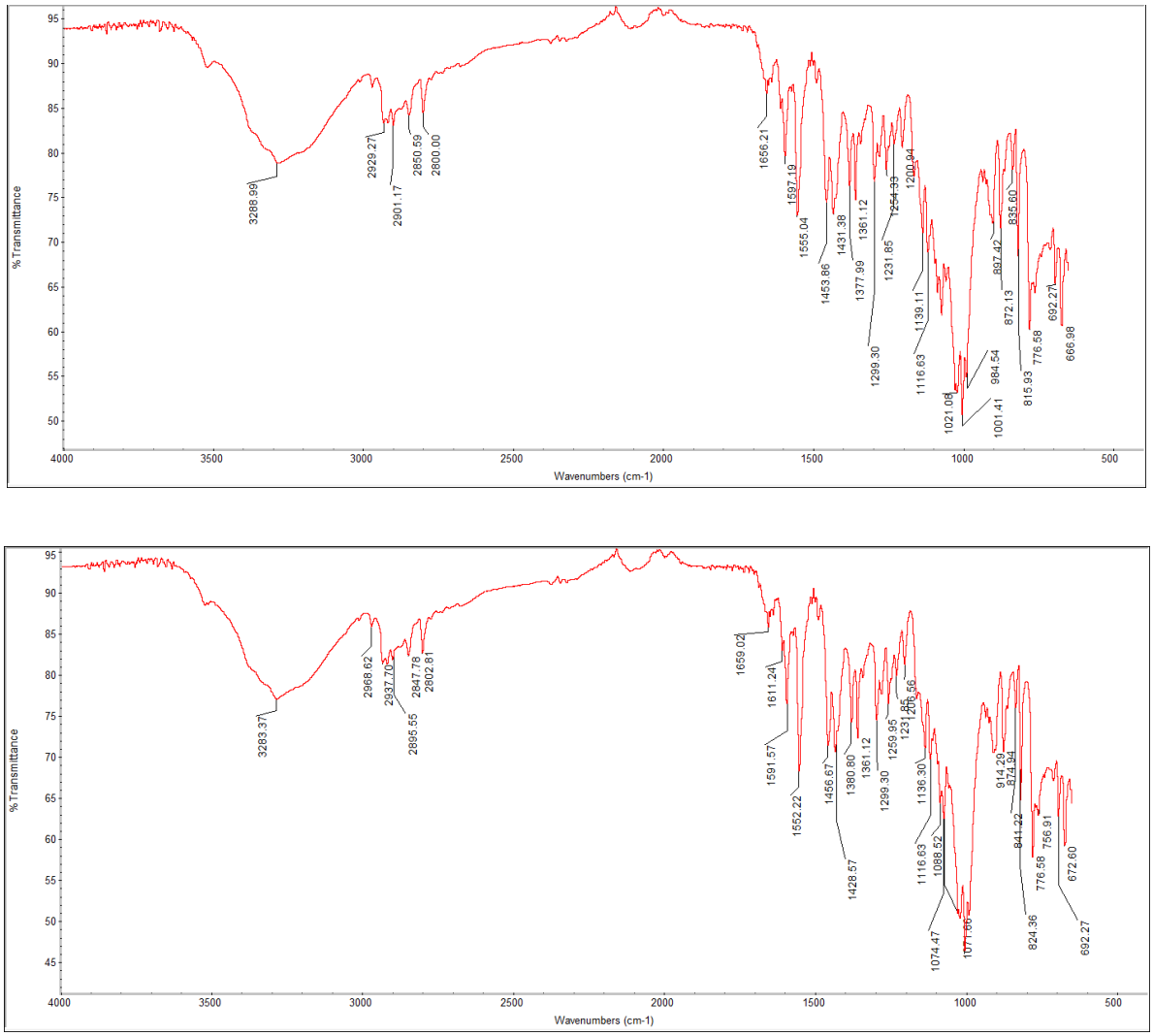


Figure. Comparative FTIR transmittance spectra of standard clozapine and anonymised

FTIR Characterization

FTIR spectra confirmed the presence of:

- Aromatic ring system
- Tertiary amine group
- Chlorinated aromatic structure

Applications of Qualitative Characterization

Qualitative characterization has broad applications in pharmaceutical sciences:

1. Quality control in pharmaceutical industries
2. Detection of counterfeit drugs
3. Stability studies
4. Regulatory submissions
5. Research and development
6. Formulation optimization
7. Academic and industrial research

CONCLUSION

Fourier Transform Infrared Spectroscopy (FTIR) plays a significant role in the qualitative characterization of clozapine tablet samples in pharmaceutical analysis. FTIR analysis provides valuable information regarding the identification of functional groups, molecular interactions, and structural integrity of the drug molecule within the formulation. The

characteristic absorption peaks observed in the FTIR spectrum confirm the presence of clozapine and help verify its chemical identity and purity. This technique is also highly useful in detecting possible interactions between the active pharmaceutical ingredient (API) and excipients used in tablet formulations.

In qualitative characterization studies, FTIR serves as an effective and reliable analytical tool for evaluating formulation compatibility and ensuring that no undesirable chemical changes occur during manufacturing or storage. The comparison of FTIR spectra of pure clozapine with marketed or formulated tablet samples helps determine whether the essential functional groups remain intact, thereby confirming formulation stability. Additionally, FTIR analysis assists in identifying impurities, degradation products, and compositional variations that may affect drug quality and therapeutic performance.

The non-destructive nature, rapid analysis time, high sensitivity, and minimal sample preparation requirements make FTIR a preferred technique in pharmaceutical research and quality control laboratories. In M.Sc. research studies, FTIR-based characterization provides a strong scientific foundation for advanced formulation development and analytical investigations. Therefore, FTIR analysis of clozapine tablet samples is essential for maintaining pharmaceutical quality, ensuring regulatory compliance, and enhancing the safety, efficacy, and reliability of drug products for patient use.

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