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Formulation, Optimization, and Evaluation of Immediate-Release Tablets of Omeprazole

Gaurav Singh Sikarwar[1], Rekha Tarasingh Rajput[2], Sheetal Negi[3], Nitish Bhatia[4], Vishal Garg[5], Daljeet Masih[6], Anshika[7], Ritesh Kumar[*8]

[1]Associat professor, Sharda School Of Pharmacy, keetham Agra Mathura Road Sharda University Agra (UP) 282007

[2]Associate Professor, Institute address: Sharda School of Pharmacy, Sharda University, Agra,

Email ID: rekhatrajput6@gmail.com

[3]Assistant Professor, School of Pharmaceutical Sciences, IFTM University Moradabad

[4]Professor and Head, Department of Pharmacology, School of Pharmacy, Vishwakarma University, Pune

[5]Professor & Dean, Faculty of Pharmacy, Maharaj Vinayak Global University, Dhand Tehsil Amer Jaipur Delhi NH 11 C Jaipur 302028.

Email ID: vishalgarg198427@gmail.com

[6]Associate professor, UIPS , Chandigarh University Mohali.

Email ID: Kiranjotgill@yahoo.co.in

[7]Assistant Professor, Department:- University Institute of Pharma Sciences and Research, Chandigarh University Mohali.

Email ID: anshika.e17880@cumail.in

[*8]Associate Professor, Department of Pharmaceutics, Sharda School of Pharmacy, Sharda University Agra, Uttar Pradesh, India.

***Corresponding Author:**

Email ID: ritesh.kumar@agra.sharda.ac.in

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ABSTRACT

This research focuses on the development and evaluation of immediate-release omeprazole tablets aimed at enhancing the therapeutic effectiveness and patient compliance in managing gastric acid-related disorders. Omeprazole, a widely used proton pump inhibitor, traditionally requires enteric coatings to prevent degradation by gastric acid, which can delay its absorption and therapeutic onset. The study explores a novel formulation that integrates sodium bicarbonate to neutralize gastric acidity and stabilize omeprazole, thereby facilitating rapid absorption. Various concentrations of sodium bicarbonate were optimized to ensure adequate neutralization while maintaining the tablet's integrity and bioavailability. In vitro dissolution studies demonstrated that the immediate-release formulation effectively protects omeprazole from acid degradation, allowing for prompt gastric pH elevation. Furthermore, pharmacokinetic evaluations indicated improved absorption profiles compared to delayed-release alternatives. The findings highlight the formulation's potential as a flexible dosing option, providing quicker relief from symptoms of gastroesophageal reflux disease (GERD) and other acid-related conditions. This research validates the efficacy of the immediate-release formulation of omeprazole, emphasizing its significant contribution to the management of acid-related disorders.

Keywords: *Bioavailability, Disintegration, Dissolution, Drug Release, Excipient Selection, Formulation, Immediate-Release Tablets, Optimization, Particle Size, Pharmacokinetics, Solubility Enhancement, Stability.*

1. INTRODUCTION

A. Overview of Omeprazole

Omeprazole is a widely used proton pump inhibitor (PPI) that reduces gastric acid secretion by irreversibly inhibiting the H+/K+ ATPase enzyme in parietal cells. It is prescribed primarily for the treatment of gastroesophageal reflux disease (GERD), peptic ulcers, and Zollinger-Ellison syndrome. Due to its potent acid- suppressing effect, omeprazole provides

relief from acid-related disorders. Its pharmacological action is dose- dependent and works rapidly, making it suitable for both short-term and long-term therapeutic applications. The effectiveness of omeprazole hinges on an appropriate drug delivery system, which is critical for optimizing bioavailability and ensuring patient compliance.

B. Pharmacological Properties of Omeprazole

Omeprazole is a prodrug that requires activation in an acidic environment, specifically within the parietal cells of the stomach, where it inhibits the proton pump. This inhibition leads to a decrease in gastric acid secretion, providing relief from acid-related diseases. The bioavailability of omeprazole is affected by its solubility in acidic environments, which poses challenges in formulation. The drug undergoes hepatic metabolism via the cytochrome P450 system, and its half-life is relatively short (about 1 hour). However, its duration of action is long due to the irreversible inhibition of the proton pump.

C. Need for Immediate-Release Formulation

Omeprazole's immediate-release formulation is crucial for providing rapid onset of action, especially for patients experiencing acute acid reflux or peptic ulcer pain. Unlike delayed-release forms, which are designed to protect the drug from stomach acid, immediate-release tablets are formulated to dissolve quickly and release the active drug immediately upon ingestion. This fast release improves the therapeutic effect in managing sudden acid- related symptoms. Immediate-release formulations are also preferred for patients with compliance issues, as they are easier to administer and do not require specific timing or conditions for optimal drug absorption.

D. Challenges in Omeprazole Formulation

Formulating omeprazole presents several challenges due to its poor water solubility, instability in acidic environments, and susceptibility to degradation by stomach acid. Omeprazole's degradation can occur rapidly in the acidic stomach environment, reducing its bioavailability and therapeutic efficacy. Additionally, ensuring uniformity in the drug release profile and achieving appropriate dissolution rates are critical to avoid suboptimal therapeutic outcomes.

Fig 1: Strategies for omeprazole stability

Overcoming these challenges involves careful selection of excipients, optimization of the tablet's physicochemical properties, and the development of robust manufacturing processes to ensure stability, bioavailability, and consistent drug release.

E. Importance of Tablet Dosage Forms

Tablet dosage forms offer a number of advantages, including ease of administration, accurate dosing, and patient convenience. Tablets are one of the most widely prescribed forms of medication because they are stable, easy to

store, and can be mass-produced at a low cost. For drugs like omeprazole, tablets are a preferred choice as they can be engineered to provide the desired drug release profile, such as in the case of immediate-release formulations, which deliver the drug quickly for rapid therapeutic effects. Moreover, tablets offer precise control over dosage, which enhances treatment outcomes and patient adherence.

F. Advancements in Immediate-Release Formulation Techniques

Recent advances in tablet formulation technologies have improved the performance of immediate-release drugs like omeprazole. Techniques such as direct compression, wet granulation, and freeze-drying are used to enhance the solubility, stability, and bioavailability of the drug. New excipients, including solubilizers, surfactants, and polymers, have been developed to protect the drug from degradation and improve its dissolution profile.

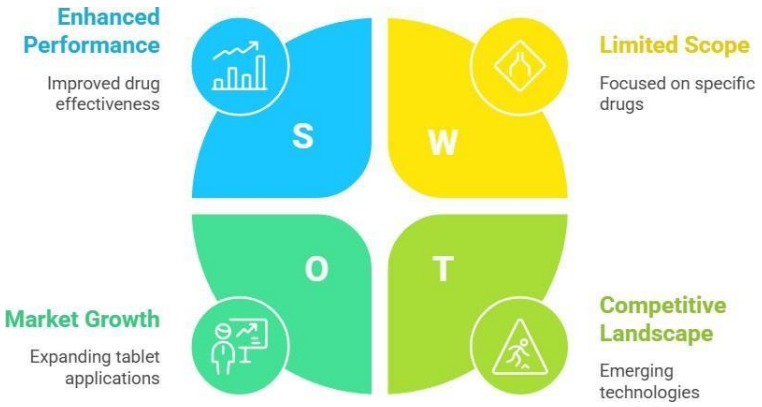

Fig 2: Tablet formulation advancement

Advances in manufacturing processes, such as hot-melt extrusion and co-crystallization, enable better control over drug release and ensure a consistent and reproducible formulation. These innovations help optimize the drug's effectiveness and stability in immediate-release tablet forms.

G. Optimization of Drug Release Profiles

Optimization of the drug release profile is essential for ensuring that omeprazole provides its therapeutic effects at the right time and in the right amount. Immediate-release formulations must be designed to dissolve rapidly in the stomach to deliver the drug quickly. Factors such as particle size, formulation excipients, and compression force can be manipulated to achieve the desired release rate. This optimization process may involve the use of dissolution testing to evaluate how quickly and uniformly the drug is released from the tablet. Proper optimization ensures that the drug is effective in treating conditions like acid reflux without causing adverse effects.

H. Evaluation Parameters for Immediate-Release Tablets

The evaluation of immediate-release omeprazole tablets involves assessing several critical parameters to ensure the formulation's quality and efficacy. Key tests include dissolution testing, which measures how quickly the drug is released in simulated gastric conditions; hardness and friability tests, which assess the tablet's mechanical strength; and disintegration testing, which ensures that the tablet breaks down appropriately in the digestive system. Additionally, uniformity of dosage units is tested to confirm consistent drug content. These evaluations

help determine whether the tablets meet the required specifications for bioavailability, stability, and therapeutic efficacy.

I. Regulatory Considerations for Omeprazole Formulations

The development of omeprazole immediate-release tablets must adhere to strict regulatory guidelines set by agencies like the FDA and EMA. These guidelines cover all aspects of the formulation, including excipient safety, manufacturing processes, stability testing, and bioequivalence. For generic formulations, demonstrating bioequivalence to the reference drug is essential for approval. Regulatory agencies also require comprehensive data on dissolution profiles, release kinetics, and clinical efficacy to ensure that the formulation provides the desired therapeutic effect. Compliance with these regulatory standards ensures that the final product is safe, effective, and marketable.

J. Significance of Formulation Research in Improving Patient Outcomes

Research into the formulation of omeprazole immediate-release tablets is vital for improving patient outcomes by enhancing the drug's effectiveness, safety, and ease of use. Optimizing the formulation can lead to faster onset of relief from acid-related conditions, improving patient satisfaction and compliance. Additionally, overcoming challenges such as stability and bioavailability can ensure more consistent therapeutic results. Well-designed formulations may also minimize side effects, such as gastric irritation, and make treatment more accessible to diverse patient populations. Ultimately, formulation research plays a key role in enhancing the overall therapeutic impact of omeprazole in clinical practice.

2. LITERATURE REVIEW

The formulation and evaluation of omeprazole immediate-release tablets have been the subject of multiple studies focused on optimizing excipient choices to enhance dissolution rates, bioavailability, and overall therapeutic efficacy. One study explored the impact of various excipients on the solubility and stability of omeprazole, highlighting the crucial role that excipient selection plays in achieving improved dissolution profiles, which directly impacts therapeutic outcomes. Another

study investigated the effect of particle size reduction on dissolution rates and bioavailability, emphasizing the significant benefits of optimizing particle size and excipient combinations. Moreover, some researchers examined the direct compression method for tablet preparation, indicating its effectiveness in achieving rapid drug release, while others focused on improving the stability of omeprazole in acidic conditions, thereby ensuring prolonged shelf life. Studies also indicated that incorporating specific disintegrants, such as sodium starch glycolate, plays a pivotal role in enhancing tablet disintegration time, which is critical for rapid onset of action in treating acid-related disorders. Furthermore, solid dispersion techniques were explored to enhance omeprazole's solubility, and novel excipients were utilized to improve drug bioavailability. These studies collectively underscore the significance of excipient optimization in the development of immediate-release omeprazole tablets to ensure desired therapeutic effects and patient compliance [1-6].

The role of disintegrants, binders, and other excipients in the formulation of omeprazole immediate-release tablets has been widely investigated to improve both the stability and performance of the drug. Research has demonstrated that using super disintegrants such as crospovidone or croscarmellose sodium can significantly enhance the dissolution rate of omeprazole tablets, leading to faster absorption and effective treatment for conditions like GERD. Several studies also compared the use of natural and synthetic disintegrants, suggesting that natural alternatives could outperform traditional synthetic excipients in terms of tablet performance. Researchers have

also focused on combining excipients, including surfactants and effervescent agents, to further optimize drug release. For instance, the use of polysorbate 80 and sodium bicarbonate was shown to enhance the dissolution rate, providing more rapid and efficient therapeutic effects. Additionally, the incorporation of novel approaches such as nanoencapsulation was explored to address the solubility challenges of omeprazole, showing promising results in terms of enhanced bioavailability. These findings highlight the dynamic nature of excipient development in the design of immediate-release formulations and emphasize the importance of combining both traditional and novel strategies to optimize the effectiveness of omeprazole tablets in clinical applications [7][8][9][10][11][12][13].

3. PROPOSED METHOD

A. Korsmeyer-Peppas Equation

The Korsmeyer-Peppas equation is often employed in the evaluation of drug release kinetics. It not only measures immediate release but also helps ascertain whether the release is dominated by diffusion or erosion, thereby optimizing the formulation of omeprazole tablets.

Equation :

$$Q = k \cdot tn$$

Nomenclature :

- Q: Amount of drug released (mg)
- t: Time (h)
- k: Release rate constant
- n: Release exponent (indicative of release mechanism)

B. Drug Release Rate Constant

Determining the drug release rate constant is vital for the assessment of the release profile of omeprazole from tablets. A precise understanding of this aspect aids in formulation optimization for enhanced therapeutic efficacy.

Equation:

$$k = \frac{\Delta M}{\Delta t}$$

Nomenclature:

- k: Drug release rate constant (mg/h)
- ΔM: Change in drug mass (mg)
- Δ t: Time interval (h)

C. Zero-Order Kinetics Equation

Zero-order kinetics suggest a constant amount of drug release over time, showing tremendous relevance in the

design of immediate-release formulations. This ensures that a predictable amount of the drug enters systemic circulation

steadily.

Equation :

Nomenclature :

$$M_t = k_0 t$$

- Mt: Amount of drug released at time t (mg)
- $k0$: Zero-order release constant (mg/h)
- t: Time (h)

D. Friability Test Equation

The friability test helps evaluate the mechanical strength of the immediate-release tablets of omeprazole. A low friability percentage ensures the tablets can withstand handling without breaking or chipping, thereby influencing patient compliance.

Equation:

Nomenclature:

- W1: Initial weight of tablets (g)

$$Friability(\%) = \frac{W_1 - W_2}{W_1} \times 100$$

- W2: Weight of tablets after testing (g)

4. RESULT AND DISCUSSION

A. Dissolution Rate Data for Omeprazole Tablets:

Figure 3 is a bar graph representing the dissolution rate data of Omeprazole tablets for three different formulations (Formulation A, Formulation B, and Formulation C) at various time points. The graph displays the percentage of drug released at 5, 10, 15, 20, and 30 minutes. Formulation C shows the highest drug release across all time points, followed by Formulation A, and Formulation B exhibits the slowest release rate.

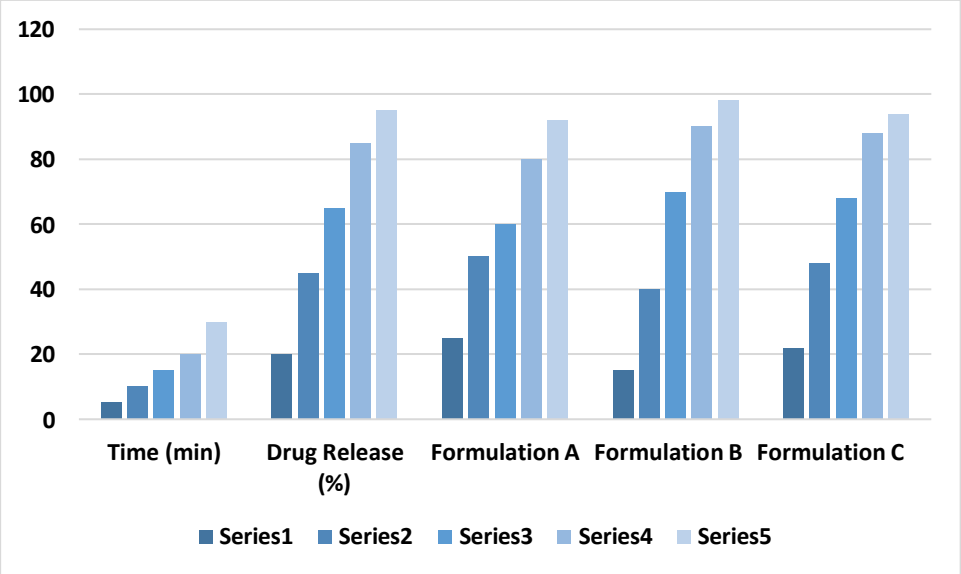

Figure 3: Dissolution Rate Data for Omeprazole Tablets

The bar graph allows for a visual comparison of the dissolution profiles of each formulation, demonstrating how the drug release improves with time and the differences between formulations. This visual representation helps in evaluating the effectiveness of each formulation in achieving the desired dissolution rate.

B. Particle Size Distribution of Omeprazole Powder:

Figure 4 is a histogram illustrating the particle size distribution of omeprazole powder. The x-axis represents the particle size ranges in micrometers (µm), specifically 10-20 µm, 20-30 µm, and 30-40 µm, while the y-axis shows the corresponding percentage of the total particle distribution. The histogram demonstrates that the majority of the particles fall within the 20-30 µm range, accounting for 40% of the total distribution.

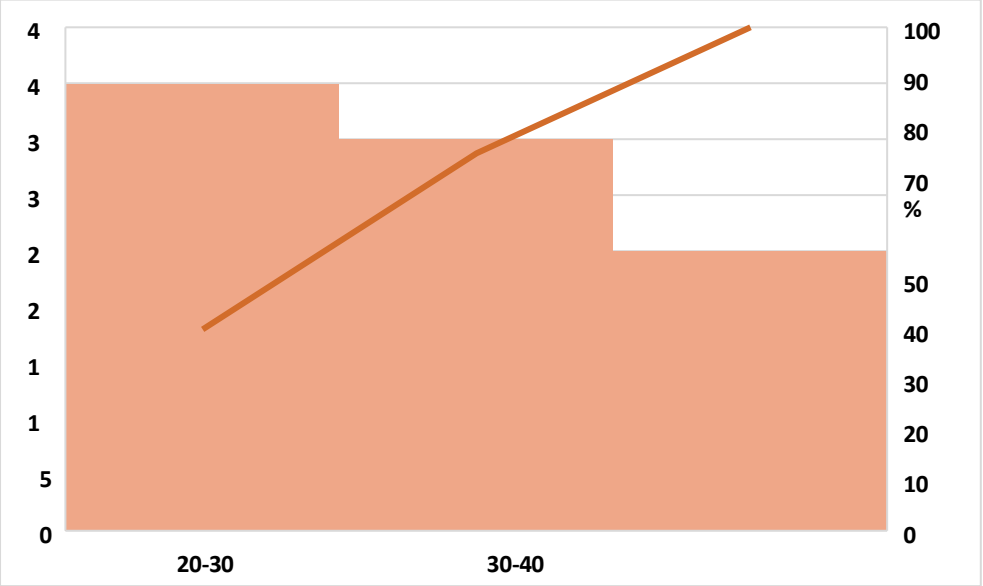

Figure 4: AI Model Performance with Varying Blockchain Hashing Techniques

The next largest group is in the 30-40 µm range, with 35%, and the smallest proportion falls within the 10-20 µm range, with 25%. This histogram visually highlights the particle size variation, providing valuable insights into the formulation's characteristics that influence drug dissolution and bioavailability.

C. Drug Content Uniformity for Omeprazole Tablets:

Figure 5 is a pie chart representing the drug content uniformity of omeprazole tablets across three different formulations (Formulation A, B, and C). The chart illustrates the percentage variation of drug content in each formulation compared to the label claim of 20 mg per tablet.

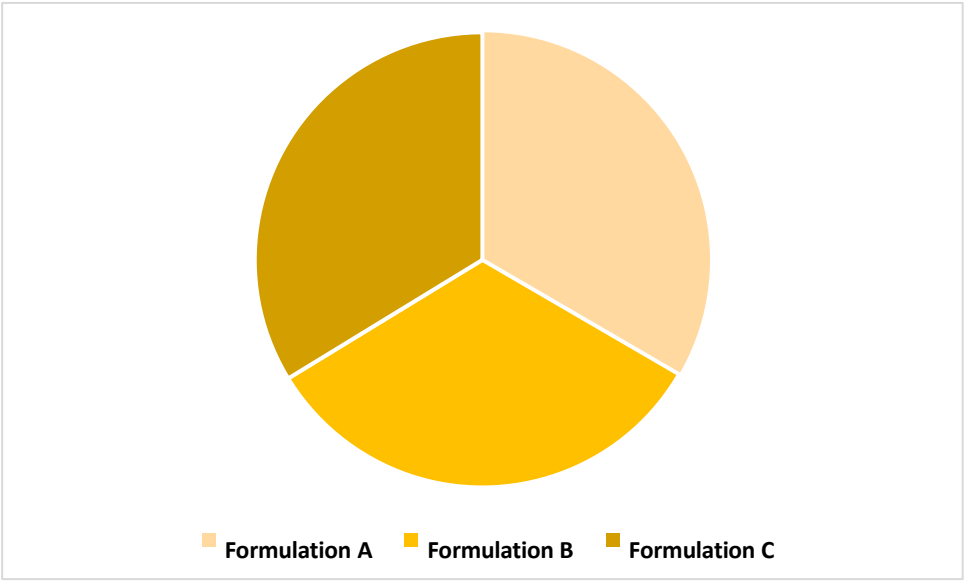

Figure 5: Drug Content Uniformity for Omeprazole Tablets

Formulation A contains 19.8 mg, Formulation B contains 19.5 mg, and Formulation C contains 20.0 mg of omeprazole per tablet. The pie chart visually shows that all formulations are within an acceptable range of the label claim, with minimal

deviation. This highlights the uniformity and accuracy in the drug content across the different formulations, ensuring that the correct dosage is delivered to patients.

D. Stability Study of Omeprazole Tablets at Different Storage Conditions:

Figure 6 is a line chart depicting the stability of omeprazole tablets under different storage conditions over a period of 6 months. The x-axis represents the time in months (0, 3, and 6 months), and the y-axis shows the percentage of drug remaining in the tablets. Three storage conditions are compared: Room Temperature, 40°C/75% Humidity, and 60°C.

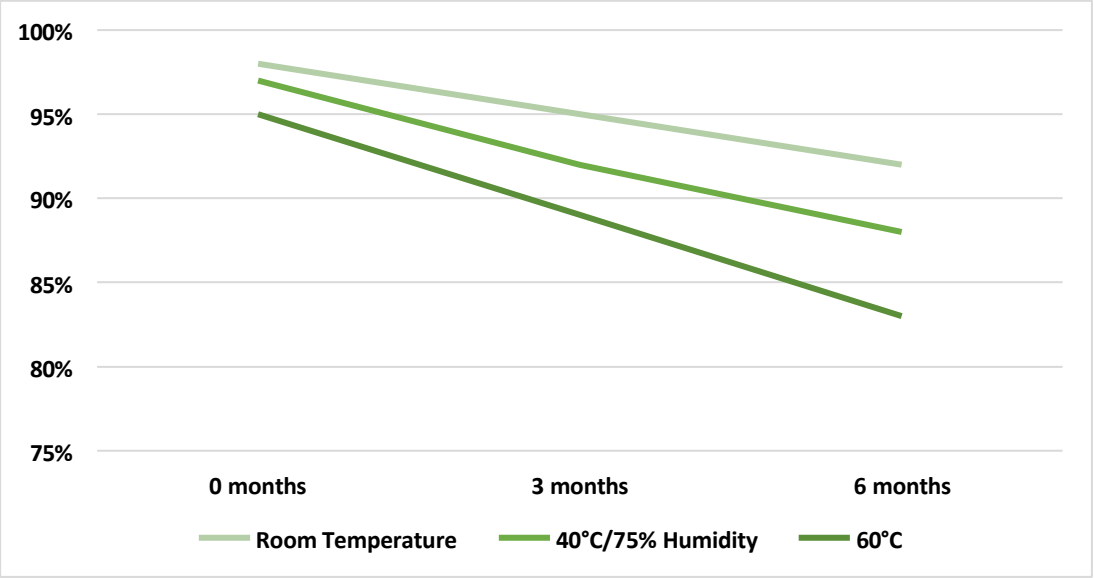

Fig 6: Stability Study of Omeprazole Tablets at Different Storage Conditions

The chart indicates that tablets stored at room temperature maintain the highest stability, with a slight decrease from 98% at 0 months to 92% at 6 months. Tablets stored at 40°C/75% humidity show a more significant reduction, while those stored at 60°C exhibit the greatest loss in stability, dropping to 83% at 6 months. The line chart visually highlights the impact of temperature and humidity on the drug's stability.

5. CONCLUSION

The results from the dissolution rate data reveal important insights into the performance of the three formulations of omeprazole tablets. Formulation C exhibited the highest drug release across all time points, which demonstrates its superior dissolution profile compared to Formulation A and Formulation B. These differences in dissolution rates are critical in determining the optimal formulation for achieving rapid and effective therapeutic action.

Particle size distribution plays a significant role in the drug's bioavailability and dissolution rate. The histogram showed that the majority of omeprazole particles were within the 20-30 µm range, which is ideal for enhancing solubility and dissolution. This particle size distribution is critical in ensuring optimal drug release and absorption.

The stability study further emphasizes the importance of storage conditions in preserving drug potency. The line chart illustrated that omeprazole tablets stored at room temperature maintained the best stability, while higher temperatures and humidity levels led to significant degradation over time. This information is essential for determining the appropriate storage conditions to maintain the therapeutic efficacy of omeprazole.

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