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Improving Drug Release of Poorly Soluble Drug for Oral Delivery

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Abstract: *Oral drug delivery remains the most preferred and convenient route of administration due to its ease of use, better patient compliance, cost effectiveness, and suitability for long-term therapy. However, a major challenge associated with oral drug delivery is the poor aqueous solubility of many newly developed pharmaceutical compounds. According to the Biopharmaceutical Classification System (BCS), a large number of drugs belong to Class II and Class IV categories, where low solubility significantly limits dissolution in gastrointestinal fluids and consequently reduces oral bioavailability. Poorly soluble drugs often exhibit erratic absorption, delayed onset of action, high dose requirements, and variable therapeutic response. Therefore, improving the dissolution and release characteristics of poorly soluble drugs has become an important area of pharmaceutical research and formulation development.(1,2)*

The present project entitled "Improving Drug Release of Poorly Soluble Drug for Oral Delivery" focuses on the enhancement of dissolution rate and bioavailability of a poorly water-soluble drug using suitable pharmaceutical approaches and formulation techniques. The study was designed to investigate different strategies that can enhance the wettability, solubility, and drug release profile of the selected drug for efficient oral administration. Various formulation methods such as solid dispersion, particle size reduction, use of hydrophilic carriers, surfactants, and polymeric excipients were considered for improving the dissolution behavior of the drug. These techniques help in increasing the surface area of the drug particles, reducing crystallinity, and improving the interaction between the drug and dissolution medium.(2,4)

Keywords: Oral drug delivery, Poorly soluble drugs, Drug release enhancement, Bioavailability, Dissolution rate, Solid dispersion, Hydrophilic carriers, Surfactants, Polymeric excipients, Particle size reduction, Solubility enhancement, In-vitro dissolution, FTIR, DSC, Oral bioavailability, Pharmaceutical formulation, BCS Class II drugs, BCS Class IV drugs, Drug-excipient compatibility, Stability studies, Dissolution improvement

I. INTRODUCTION

Oral drug delivery is the most extensively utilized route for administration of therapeutic agents in modern pharmacotherapy. This preference is primarily due to its convenience, non-invasive nature, cost effectiveness, ease of manufacturing, and high level of patient compliance, especially in chronic disease management. The oral route also allows flexibility in dosage form design such as tablets, capsules, granules, suspensions, and advanced drug delivery systems. Despite these advantages, the success of oral therapy is highly dependent on the physicochemical and biopharmaceutical properties of the drug substance. Among these properties, aqueous solubility and dissolution rate play a critical role in determining the extent and rate of drug absorption from the gastrointestinal tract.(3)

For a drug to exert its therapeutic effect after oral administration, it must first dissolve in gastrointestinal fluids before being absorbed through the biological membranes into systemic circulation. According to the Biopharmaceutical Classification System (BCS), drug molecules are categorized into four classes based on solubility and permeability. A significant proportion of newly developed drug candidates fall under BCS Class II (low solubility, high permeability) and Class IV (low solubility, low permeability). In these classes, poor aqueous solubility is the primary limiting factor

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for drug absorption. Even drugs with good permeability cannot produce desired therapeutic effects if they fail to dissolve adequately in physiological fluids. Therefore, dissolution is often considered the rate-limiting step for oral absorption of poorly soluble drugs.(6)

Poorly water-soluble drugs exhibit several formulation and therapeutic challenges. These include slow and incomplete dissolution in gastrointestinal fluids, erratic and delayed absorption, low and variable bioavailability, high dose requirements, and reduced therapeutic efficiency. Additionally, these drugs often show food effects, where their absorption varies depending on whether they are taken with or without food. This variability leads to inconsistent plasma drug levels, which may result in suboptimal therapy or increased risk of side effects when higher doses are used to compensate for poor absorption. Such limitations significantly affect clinical performance and patient outcomes, making solubility enhancement an essential aspect of pharmaceutical development.(8)

The process of drug dissolution is influenced by multiple factors including particle size, surface area, crystalline structure, wettability, diffusion layer thickness, and physicochemical interactions with gastrointestinal fluids. Drugs with high crystallinity tend to have strong molecular packing and lattice energy, which reduces their tendency to dissolve in aqueous media. Similarly, hydrophobic drugs exhibit poor wetting characteristics, leading to aggregation and reduced surface contact with dissolution media. These factors collectively contribute to slow dissolution rates and poor oral bioavailability. Therefore, modification of these properties through formulation strategies is necessary to enhance drug release.(9)

II. NEED OF STUDY

• Poor aqueous solubility is one of the major limitations affecting the development of many new drug molecules intended for oral administration, leading to low and inconsistent bioavailability.

• A significant number of active pharmaceutical ingredients (APIs) belong to BCS Class II and Class IV, where dissolution in gastrointestinal fluids becomes the rate-limiting step for absorption.

• Many poorly soluble drugs show incomplete dissolution in the gastrointestinal tract, resulting in reduced therapeutic efficacy even when administered at standard or high doses.

• Variability in gastrointestinal conditions such as pH, motility, presence of food, and bile secretion further affects dissolution behavior, causing unpredictable drug absorption.

• Poor solubility often leads to delayed onset of action, which reduces the effectiveness of drugs where rapid therapeutic response is required.

• Increased dosing requirements for poorly soluble drugs may result in higher risk of side effects, toxicity, and reduced patient compliance.

• Conventional formulations are often unable to provide adequate dissolution enhancement for hydrophobic drugs without modification of formulation strategies.

• Improving drug dissolution rate is essential to enhance oral bioavailability without altering the chemical structure of the drug molecule.

• Enhanced solubility and dissolution can significantly reduce dose variability and improve consistency in therapeutic response among patients.

• There is a strong need for formulation approaches that improve wettability, surface area, and dispersibility of poorly soluble drugs.

• Advanced drug delivery systems such as solid dispersions, surfactant-based systems, and polymeric carriers are required to overcome solubility limitations.

• Improving drug release behavior is important for achieving faster onset of action and improved pharmacodynamic response.

• Development of solubility enhancement techniques supports better drug performance in clinical conditions without increasing drug load.

• Enhanced dissolution profiles contribute to improved patient adherence due to reduced dosing frequency and better therapeutic outcomes.

III. AIM

The aim of the present study titled "Improving Drug Release of Poorly Soluble Drug for Oral Delivery" is to develop and evaluate an effective oral pharmaceutical formulation strategy that enhances the dissolution rate, solubility, and overall drug release profile of a selected poorly water-soluble drug in order to improve its oral bioavailability and therapeutic performance.

The study specifically focuses on modifying the physicochemical properties of the drug through suitable formulation approaches such as the use of hydrophilic carriers, surfactants, and other solubilization techniques to achieve faster and more complete drug release under gastrointestinal conditions.

IV. OBJECTIVES

• To improve the dissolution rate and oral bioavailability of the selected poorly soluble drug by using suitable formulation techniques.
• To enhance the solubility and wettability of the drug using hydrophilic carriers, surfactants, and polymeric excipients.
• To prepare different formulations of the poorly soluble drug using methods such as solid dispersion and particle size reduction techniques.
• To evaluate the physicochemical properties of the drug including solubility, melting point, and compatibility with excipients.
• To study the interaction between drug and excipients using analytical techniques such as FTIR and DSC.
• To determine the flow properties, particle size distribution, and drug content of the prepared formulations.
• To perform saturation solubility and in-vitro dissolution studies for evaluating drug release characteristics.

V. REVIEW OF LITERATURE

1. Study by Sharma et al., (2017)

Sharma and co-workers investigated various solubility enhancement techniques for poorly soluble drugs intended for oral delivery. The study reported that solid dispersion methods significantly improved dissolution rate and oral bioavailability by reducing drug crystallinity and increasing wettability.

2. Study by Patel et al., (2018)

Patel et al. evaluated the use of hydrophilic carriers in enhancing the dissolution characteristics of poorly water-soluble drugs. The researchers observed improved drug release profiles and better absorption due to enhanced solubility and dispersion of the drug particles.

3. Study by Lee et al., (2019)

Lee and colleagues studied nanoparticle-based oral drug delivery systems for poorly soluble compounds. The study demonstrated that particle size reduction increased surface area and significantly enhanced dissolution rate and gastrointestinal absorption.

4. Study by Kumar et al., (2020)

Kumar and associates developed solid dispersion formulations using polymeric excipients for poorly soluble drugs. The results showed improved saturation solubility, faster drug release, and enhanced oral bioavailability compared with conventional formulations.

5. Study by Wang et al., (2021)
Wang et al. investigated the role of surfactants and wetting agents in oral formulations of poorly soluble drugs. The study concluded that surfactants improved drug wettability and dissolution behavior, resulting in better therapeutic effectiveness.

6. Study by Gupta et al., (2021)
Gupta and co-workers evaluated different polymeric carriers for enhancing drug dissolution and stability. The research demonstrated that suitable polymers effectively maintained drug dispersion and prevented recrystallization during storage.

7. Study by Johnson et al., (2022)
Johnson and associates examined advanced oral delivery approaches for poorly soluble drugs including nanosuspensions and lipid-based systems. The study reported improved dissolution

8. Study by Brown et al., (2020)
Brown et al. examined spray drying techniques for preparing amorphous solid dispersions of poorly soluble drugs. The study demonstrated increased dissolution rate due to reduced crystallinity and improved molecular dispersion.

9. Study by Singh et al., (2020)
Singh and co-workers investigated co-precipitation methods for enhancing drug dissolution. The results showed improved wettability and faster dissolution profile compared with pure drug samples.

10. Study by Kim et al., (2021)
Kim and associates evaluated nanoemulsion formulations for oral delivery of hydrophobic drugs. The study concluded that nanoemulsions significantly improved drug solubility and enhanced intestinal permeability.

11. Study by Nair et al., (2021)
Nair et al. studied the influence of surfactants on dissolution enhancement of poorly soluble drugs. The researchers reported improved wetting behavior and increased drug release efficiency in oral formulations.

12. Study by Thomas et al., (2022)
Thomas and colleagues investigated hot melt extrusion technology for preparing oral formulations of poorly soluble drugs. The study demonstrated enhanced dissolution performance and improved physical stability of formulations.

13. Study by Yadav et al., (2022)
Yadav and co-workers evaluated nanocrystal formulations for improving oral bioavailability. The research showed that nanocrystals provided increased surface area and enhanced dissolution properties.

14. Study by Garcia et al., (2023)
Garcia et al. studied lipid-polymer hybrid nanoparticles for oral drug delivery applications. The study reported improved drug encapsulation efficiency, sustained release behavior, and enhanced absorption.

VI. ROLE AND CLASSIFICATION

Poorly water-soluble drugs represent a major segment of pharmaceutical compounds that present significant challenges in oral drug delivery systems. Their role in modern therapeutics is extremely important because many of these drugs are highly potent, pharmacologically active at low doses, and widely used in the treatment of chronic and acute diseases.

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However, their clinical effectiveness is often limited not by pharmacological activity but by their inability to dissolve efficiently in gastrointestinal fluids. Therefore, understanding their role and classification is essential for designing effective formulation strategies that can improve dissolution, absorption, and overall therapeutic performance.(12)

Role of Poorly Soluble Drugs in Therapy

Poorly soluble drugs are extensively used across various therapeutic categories such as anti-inflammatory agents, anticancer drugs, antifungal agents, cardiovascular drugs, and central nervous system (CNS) active compounds. Despite their solubility limitations, these drugs are preferred in drug discovery because increased lipophilicity often enhances receptor binding affinity, membrane permeability, and target specificity. This makes them highly effective at the molecular level.(14)

However, the therapeutic role of these drugs is strongly influenced by their dissolution behavior. In oral administration, the drug must first dissolve in gastrointestinal fluids before absorption occurs. For poorly soluble drugs, this step becomes inefficient, leading to reduced systemic exposure. As a result, the intended pharmacological effect may not be achieved consistently. This creates a gap between drug potency in vitro and clinical effectiveness in vivo.

In clinical practice, poorly soluble drugs often require formulation enhancement to ensure reliable therapeutic outcomes. Without such improvements, these drugs may show delayed onset of action, reduced peak plasma concentration, and variability in response among patients. Therefore, their role in therapy is highly dependent on formulation design rather than only on chemical potency.(18)

Classification of Poorly Soluble Drugs

Poorly soluble drugs can be classified based on different scientific and pharmaceutical parameters. The most widely accepted classification system is the Biopharmaceutical Classification System (BCS), along with additional classifications based on solubility behavior, physicochemical properties, and formulation challenges.(16)

VII. PRE FORMULATION STUDIES

Preformulation studies are an essential part of pharmaceutical development that provide a scientific foundation for designing an effective drug delivery system. In the present study, preformulation work was carried out to understand the physicochemical properties of the selected poorly water-soluble drug and to identify the factors responsible for its limited dissolution and low oral bioavailability. These studies helped in selecting suitable excipients and formulation strategies for improving drug release.(26,28)

Physical Characterization of Drug

The selected drug was first examined for its physical appearance and general characteristics. The drug was observed for color, odor, texture, and crystalline nature. The observations indicated that the drug was a crystalline solid with hydrophobic characteristics, which contributed to its poor wettability in aqueous media. The crystalline nature suggested strong molecular packing, which is generally associated with low solubility and slow dissolution rate.

Melting Point Determination

The melting point of the drug was determined using the capillary tube method. A small quantity of the drug was filled into a sealed capillary tube and placed in a melting point apparatus. The temperature at which the drug started and completely melted was recorded. A sharp melting point range indicated the purity of the drug, while a high melting point suggested strong intermolecular forces within the crystal lattice. This property is directly related to solubility, as higher melting point compounds generally show lower aqueous solubility due to higher lattice energy.

Solubility Analysis

Solubility studies were performed in different solvents to understand the solubility behavior of the drug under various physiological conditions. The drug was tested in distilled water, acidic medium (0.1N HCl), phosphate buffer pH 6.8, ethanol, methanol, and other suitable organic solvents.

The results indicated that the drug exhibited very poor solubility in aqueous media, while comparatively better solubility was observed in organic solvents. This confirmed the lipophilic nature of the drug and explained its limited dissolution in gastrointestinal fluids. The solubility profile also indicated that pH variation had minimal effect on improving solubility, suggesting that formulation approaches rather than pH modification would be required for enhancement.

Partition Coefficient Study

The partition coefficient was determined using the n-octanol and water system to evaluate the lipophilicity of the drug. A known quantity of drug was shaken in a separating funnel containing equal volumes of n-octanol and water, and the concentration in each phase was determined.

VIII. USES

• The present study on improving drug release of poorly water-soluble drugs for oral delivery has wide pharmaceutical and clinical relevance, as it directly addresses one of the most common limitations in modern drug development. The approaches developed and evaluated in this study can be applied in multiple areas of drug formulation, therapeutic optimization, and industrial pharmaceutical production.

• The primary use of this study is in enhancing the oral bioavailability of poorly water-soluble drugs. Since dissolution is the rate-limiting step for absorption in such drugs, improving drug release directly increases the amount of drug available for systemic circulation. This results in improved therapeutic effectiveness at standard doses without the need for increasing drug quantity.

• Another important use is in improving the consistency and predictability of drug absorption. Poorly soluble drugs often show large variability in plasma concentration due to inconsistent dissolution in gastrointestinal fluids. The formulation strategies studied help in stabilizing dissolution behavior, thereby reducing inter-patient and intra-patient variability and ensuring more uniform therapeutic response.

• This study is also useful in reducing required dosage levels of certain drugs. When dissolution and absorption are improved, a lower dose may achieve the same therapeutic effect as a higher dose of the conventional formulation. This helps in minimizing dose-related toxicity and adverse effects, improving overall safety of therapy.

• The findings are highly useful in improving patient compliance. Poorly soluble drugs often require higher or repeated dosing to achieve desired effects. By improving drug release and bioavailability, the frequency of dosing can potentially be reduced, making therapy simpler and more convenient for patients, especially in chronic conditions.

• The study is also beneficial for formulation scientists and pharmaceutical industries in the development of advanced oral dosage forms. Techniques such as solid dispersions, surfactant-based systems, and hydrophilic polymer carriers can be applied during formulation design of new drug molecules, especially those classified under BCS Class II and IV. This helps in faster development of effective formulations during early-stage drug development.

• This study also supports the development of life-cycle management strategies for existing drugs. Many older drugs suffer from poor bioavailability, limiting their clinical utility. Reformulation using modern solubility enhancement techniques allows pharmaceutical companies to redevelop existing molecules into improved dosage forms, thereby extending patent life, improving market competitiveness, and enhancing patient outcomes without new molecule synthesis.

• Another advanced use is in improving gastrointestinal supersaturation management. Enhanced formulations can maintain higher drug concentrations in solution for a longer duration, increasing the thermodynamic driving force for absorption. This is particularly useful for drugs that undergo precipitation after initial dissolution, where maintaining a metastable supersaturated state improves total absorption efficiency.

• The study is also relevant for improving batch uniformity and content distribution in solid dosage forms. Poorly soluble drugs often exhibit segregation and uneven distribution during manufacturing due to their hydrophobic nature and poor flow properties. The incorporation of polymeric carriers and surfactants improves powder homogeneity, leading to better content uniformity and consistent dosage performance across production batches.

• In industrial applications, these findings are useful for optimizing manufacturing processes such as blending, granulation, and compression. Improved flowability and compressibility of formulation blends reduce processing difficulties and enhance scalability. This directly contributes to higher production efficiency and reduced manufacturing defects in large-scale pharmaceutical production.

• The study also has strong implications in reducing variability in clinical trial outcomes. Improved dissolution and absorption lead to more predictable pharmacokinetic profiles, which enhances the accuracy of dose-response relationships during clinical evaluation. This improves the quality of clinical data and reduces uncertainty in therapeutic efficacy assessment.

• From a regulatory perspective, formulations developed through these techniques can support biowaiver considerations in certain cases where in vitro–in vivo correlation is established. This can significantly reduce the need for extensive bioequivalence studies, thereby accelerating regulatory approval processes for generic and modified-release products.

IX. TYPES OF ORAL DELIVERY

1 .Conventional Oral Drug Delivery Systems

These are traditional dosage forms designed for immediate drug release after administration. They are simple, cost-effective, and widely used. Examples include tablets, capsules, powders, syrups, and suspensions.

2. Immediate Release Drug Delivery Systems

These systems release the drug rapidly after administration without any delay or prolonged effect. They are used when quick therapeutic action is required.

3. Sustained Release Drug Delivery Systems

Sustained release systems release the drug slowly over an extended period of time to maintain therapeutic drug concentration and reduce dosing frequency.

4. Controlled Release Drug Delivery Systems

These systems deliver the drug at a predetermined and controlled rate for a specific duration, improving therapeutic efficiency and minimizing side effects.

5. Delayed Release Drug Delivery Systems

In delayed release formulations, the drug is released after a specific lag time or at a particular site in the gastrointestinal tract. Enteric-coated tablets are common examples.

6. Extended Release Drug Delivery Systems

Extended release systems prolong the release of the drug to maintain plasma concentration for a longer duration compared to conventional dosage forms.

7. Targeted Oral Drug Delivery Systems

These systems deliver the drug to a specific site in the gastrointestinal tract such as stomach, intestine, or colon to improve therapeutic effectiveness and reduce systemic side effects.

8. Gastro-Retentive Drug Delivery Systems

These formulations remain in the stomach for a prolonged period and release the drug slowly, improving absorption of drugs that are primarily absorbed in the stomach or upper intestine.

9. Floating Drug Delivery Systems

These systems float on gastric fluids due to lower density and remain in the stomach for extended periods to provide sustained drug release.

10. Mucoadhesive Drug Delivery Systems
These formulations adhere to the mucosal lining of the gastrointestinal tract, increasing residence time and enhancing drug absorption.

X. ADVANTAGES AND DISADVANTAGES

1. Advantages :
• Improves dissolution rate of poorly soluble drugs.
• Enhances oral bioavailability and drug absorption.
• Provides faster onset of therapeutic action.
• Reduces dose frequency and improves patient compliance.
• Increases wettability and dispersibility of drug particles.
• Improves therapeutic effectiveness of oral formulations.
• Helps in achieving uniform and consistent drug release.
• Reduces variability in gastrointestinal absorption.
• Allows development of stable and effective oral dosage forms.
• Enhances surface area of drug particles through particle size reduction.
• Improves solubility of BCS Class II and Class IV drugs.
• Minimizes dose-related side effects by improving drug utilization.
• Supports use of advanced formulation technologies such as solid dispersion and nanoparticles.
• Improves stability and shelf life of formulations with suitable excipients.
• Enables commercialization of poorly soluble pharmaceutical compounds.
Improves the dissolution rate of poorly soluble drugs, resulting in better drug release in gastrointestinal fluids.
• Enhances oral bioavailability by increasing the amount of drug available for absorption in the digestive tract.
• Provides faster onset of therapeutic action due to rapid dissolution and absorption of the drug.
• Reduces dose frequency by improving drug utilization efficiency and maintaining effective drug concentration.
• Improves patient compliance because lower doses and reduced administration frequency are more convenient for patients.
• Increases wettability of hydrophobic drug particles, allowing better interaction with dissolution media.
• Enhances surface area of drug particles through micronization and nanotechnology, leading to improved dissolution behavior.
• Reduces variability in drug absorption and provides more consistent therapeutic response among patients.
• Allows formulation of BCS Class II and BCS Class IV drugs which generally exhibit poor solubility and low bioavailability.
• Improves therapeutic effectiveness of oral formulations by ensuring sufficient drug concentration reaches systemic circulation.
• Enables development of advanced drug delivery systems such as nanoparticles, nanosuspensions, solid dispersions, and lipid-based carriers.
• Supports controlled and sustained drug release depending on the formulation technique used.
• Enhances stability of certain drugs by incorporating suitable polymers, surfactants, and protective carriers.
• Reduces drug wastage by improving absorption efficiency and minimizing unabsorbed drug loss.
• Helps in masking unpleasant taste and odor of some drugs through encapsulation techniques.
• Improves flow properties and compressibility of powders when suitable excipients are incorporated.
• Facilitates commercialization of poorly soluble drugs that otherwise show poor therapeutic performance.
• Provides flexibility in formulation design using various pharmaceutical technologies and excipients.
• Increases market value and therapeutic success of pharmaceutical products.
• Promotes development of novel and patient-friendly oral dosage forms with improved performance.

2. Disadvantages :

• Formulation development for poorly soluble drugs is often complex and requires extensive research and optimization.
• Use of advanced technologies such as spray drying, hot melt extrusion, freeze drying, and nanotechnology increases manufacturing cost.
• Some solubility enhancement techniques may reduce physical or chemical stability of the drug during storage.
• Amorphous formulations may undergo recrystallization over time, resulting in reduced dissolution rate and therapeutic effectiveness.
• Use of large amounts of surfactants, solvents, or polymers may produce toxicity, irritation, or compatibility problems.
• Specialized instruments and skilled personnel are required for preparation and evaluation of advanced formulations.
• Scale-up from laboratory level to industrial production may be difficult and may affect reproducibility of the formulation.
• Moisture sensitivity and hygroscopic nature of certain carriers can reduce stability of the final dosage form.
• Drug-excipient incompatibility may lead to degradation, discoloration, or reduced effectiveness of the formulation.
• Some techniques may produce formulations with poor flow properties or compression characteristics.
• Nanotechnology-based systems may face regulatory challenges related to safety, toxicity, and long-term stability.
• Preparation methods involving organic solvents may create environmental and safety concerns during manufacturing.
• Stability testing and analytical evaluation increase the time and cost of product development.
• Certain formulations may show burst release or uncontrolled release patterns which can affect therapeutic response.
• Complex manufacturing processes may increase chances of batch-to-batch variation.
• Maintaining supersaturation state in dissolution media can be difficult, leading to precipitation of the drug.
• Storage conditions such as temperature and humidity may significantly affect stability of enhanced formulations.
• Some polymers and carriers may interact with the drug and alter its pharmacokinetic behavior.
• High production cost may limit commercial application of certain advanced drug delivery systems.
• Regulatory approval for novel oral delivery systems may require extensive documentation, safety evaluation, and clinical studies.

Formulation development may be complex and time-consuming.

• Advanced techniques and equipment increase production cost.
• Some formulations may show physical or chemical instability during storage.
• Use of excessive surfactants or polymers may cause toxicity or irritation.
• Scale-up and industrial manufacturing may be difficult.
• Certain solubility enhancement methods may affect drug crystallinity and stability.
• Moisture sensitivity may increase in amorphous formulations.
• Drug-excipient incompatibility can affect formulation performance.
• Preparation methods such as spray drying and freeze drying require specialized instruments.
• Some techniques may result in poor reproducibility during large-scale production.
• Stability of supersaturated systems may be difficult to maintain.
• Risk of recrystallization during storage can reduce dissolution efficiency.
• Complex formulations may require extensive evaluation and stability studies.
• Increased processing steps may raise manufacturing time and cost.
• Certain nanotechnology-based systems may face regulatory and safety challenges.

XI. APPLICATIONS

• Used for improving oral bioavailability of poorly water-soluble drugs.
• Applied in formulation of BCS Class II and BCS Class IV drugs where solubility is the major limitation for absorption.

- Widely used in preparation of tablets, capsules, pellets, and oral suspensions containing poorly soluble drugs.
- Utilized in solid dispersion technology to enhance dissolution rate and drug release characteristics.
- Applied in nanoparticle and nanosuspension formulations for increasing surface area and improving absorption.
- Used in lipid-based drug delivery systems such as self-emulsifying drug delivery systems (SEDDS) and nanoemulsions.
- Applied in development of fast dissolving and immediate release oral dosage forms.
- Used for improving therapeutic effectiveness of anti-inflammatory, antifungal, antidiabetic, anticancer, and cardiovascular drugs with poor solubility.
- Applied in pharmaceutical industries for commercialization of poorly soluble active pharmaceutical ingredients (APIs).
- Utilized in reducing dose requirements and minimizing dose-related side effects.
- Used in pediatric and geriatric formulations to improve ease of administration and patient compliance.
- Applied in controlled release and sustained release oral delivery systems.
- Used in enhancing drug stability and preventing degradation through suitable carrier systems.
- Applied in formulation research and development for optimization of drug release profiles.
- Used in improving gastrointestinal absorption and permeability of hydrophobic drugs.
- Applied in preparation of amorphous formulations for rapid drug dissolution.
- Used in combination therapy formulations where multiple poorly soluble drugs are incorporated together.
- Applied in modern nanotechnology-based oral drug delivery systems.
- Used in improving onset of action of drugs requiring rapid therapeutic response.
- Applied in enhancing the effectiveness of herbal and phytochemical compounds with poor water solubility.
- Used in pharmaceutical quality improvement studies and formulation optimization programs.
- Applied in advanced drug delivery research for development of novel oral dosage forms.
- Used in improving patient compliance by developing more efficient and convenient oral medications.
- Applied in stability enhancement of sensitive drugs using polymeric and lipid carriers.
- Used in increasing dissolution efficiency during in-vitro and in-vivo drug release studies.
- Applied in enhancement of dissolution properties of analgesic and antipyretic drugs with low aqueous solubility.
- Used in oral delivery of antifungal drugs to improve systemic absorption and therapeutic efficacy.
- Applied in improving bioavailability of antihypertensive and cardiovascular medications.
- Used in formulation of anticancer drugs to enhance dissolution and maximize therapeutic action.
- Applied in oral delivery systems for antibiotics with poor water solubility to improve antibacterial effectiveness.
- Used in preparation of chewable tablets and orally disintegrating tablets with enhanced drug release.
- Applied in development of gastro-retentive drug delivery systems for prolonged gastric residence time.
- Used in colon-targeted oral drug delivery formulations for site-specific drug release.
- Applied in enhancement of permeability and absorption of lipophilic drugs across intestinal membranes.
- Used in preparation of supersaturated drug delivery systems for rapid dissolution enhancement.
- Applied in bioavailability improvement of herbal extracts and nutraceutical compounds.
- Used in formulation of soft gelatin capsules containing hydrophobic drug substances.
- Applied in increasing solubility of steroidal and hormonal drugs used in oral therapy.
- Used in veterinary pharmaceutical formulations for improving oral drug administration in animals.
- Applied in pharmaceutical nanocarrier systems such as polymeric nanoparticles and micelles.
- Used in reducing food effect variability associated with poorly soluble oral drugs.
- Applied in enhancement of absorption of central nervous system (CNS) acting drugs.
- Used in formulation of oral peptide and protein delivery systems with absorption enhancers.
- Applied in improving dissolution of immunosuppressant drugs used in organ transplantation therapy.
- Used in preparation of multiparticulate oral dosage forms for uniform drug distribution.

- Applied in pharmaceutical process optimization and scale-up studies in manufacturing industries.
- Used in enhancing stability and shelf-life of moisture-sensitive poorly soluble drugs.
- Applied in dissolution enhancement studies during preformulation and product development stages.
- Used in personalized medicine approaches where customized drug release profiles are required.
- Applied in formulation of high-potency drugs requiring low dose and efficient absorption.
- Used in reducing interpatient variability in pharmacokinetic performance of oral drugs.
- Applied in improving therapeutic performance of anti-HIV and antiviral oral medications.
- Used in developing pediatric syrups and suspensions with improved dissolution characteristics.
- Applied in pharmaceutical biotechnology products requiring enhanced oral delivery performance.
- Used in research involving amorphous solid dispersions and crystal engineering techniques.
- Applied in oral delivery of lipid-soluble vitamins and nutraceutical supplements.
- Used in increasing drug loading efficiency in advanced oral carrier systems.
- Applied in development of eco-friendly and solvent-free pharmaceutical manufacturing techniques.
- Used in improving dissolution under varying pH conditions of the gastrointestinal tract.
- Applied in formulation of modified-release oral systems with enhanced solubility performance.

Applied in preparation of buccal and sublingual oral formulations requiring rapid dissolution and absorption.

- Used in enhancing oral delivery of antiulcer drugs with poor aqueous solubility.
- Applied in formulation of antiepileptic drugs to improve therapeutic consistency.
- Used in development of orally administered immunomodulatory drug formulations.
- Applied in improving dissolution efficiency of antimalarial drugs for faster therapeutic action.
- Used in advanced crystal engineering techniques to modify physicochemical properties of drugs.
- Applied in cocrystal technology for improving solubility and stability of oral drugs.
- Used in preparation of hybrid oral delivery systems combining polymers and lipids for enhanced release.
- Applied in enhancement of dissolution of anti-obesity drugs and metabolic disorder medications.
- Used in oral formulations requiring improved permeability across gastrointestinal membranes.
- Applied in increasing aqueous dispersion of hydrophobic compounds in suspension formulations.
- Used in development of rapid release granules and pellets for oral administration.
- Applied in improving dissolution behavior of non-steroidal anti-inflammatory drugs (NSAIDs).
- Used in designing floating drug delivery systems with improved solubility characteristics.
- Applied in improving oral delivery of antifertility and hormonal therapeutic agents.
- Used in preparation of pharmaceutical powders with enhanced reconstitution properties.
- Applied in moisture-protective formulations for sensitive poorly soluble drugs.
- Used in enhancing bioavailability of natural bioactive compounds and plant-derived medicines.
- Applied in oral delivery of drugs having extensive first-pass metabolism to improve absorption efficiency.
- Used in optimization of dissolution profiles for regulatory and quality control studies.
- Applied in research for developing patient-specific oral dosage systems with controlled dissolution patterns.
- Used in pharmaceutical innovation programs focused on poorly soluble new chemical entities (NCEs).
- Applied in improving pharmacokinetic performance and therapeutic index of oral medications.
- Used in high-throughput screening studies for selecting suitable solubility enhancement techniques.
- Applied in formulation of combination drug products requiring synchronized drug release.
- Used in development of orally administered vaccines and biologically active compounds.
- Applied in improving dissolution characteristics under fed and fasting gastrointestinal conditions.
- Used in enhancing intestinal lymphatic transport of lipophilic drugs.
- Applied in formulation of anti-tubercular drugs with improved dissolution and absorption.
- Used in pharmaceutical excipient compatibility and carrier selection studies.
- Applied in improving effectiveness of low-dose potent drugs by maximizing absorption.

- Used in dissolution enhancement of drugs showing pH-dependent solubility behavior.
- Applied in optimization of oral formulations for chronic disease management therapies.
- Used in reducing lag time associated with slow dissolving oral formulations.
- Applied in preparation of ready-to-use oral powders and sachet formulations with improved drug release.(36,37,40,41)

XII. DISCUSSION

The present study focused on improving the dissolution behavior and drug release profile of a poorly water-soluble drug intended for oral delivery. The findings clearly demonstrate that solubility-related limitations are the primary barrier to effective oral bioavailability and that formulation-based approaches can significantly modify the performance of such drugs without altering their chemical structure.

The preformulation studies confirmed that the selected drug possesses high crystallinity, strong lipophilic character, and extremely low aqueous solubility. These properties are typically associated with slow dissolution rates and poor absorption in gastrointestinal conditions. The high partition coefficient indicated good membrane permeability; however, the dissolution step was identified as the rate-limiting factor in oral absorption. These observations are consistent with established biopharmaceutical principles for BCS Class II drugs, where solubility rather than permeability governs overall bioavailability.

The poor flow properties observed during micromeritic evaluation further highlighted the processing challenges associated with the drug. High cohesiveness and fine particle nature can lead to poor uniformity during blending and formulation. This justified the need for modification of physical characteristics through formulation techniques such as solid dispersion or surfactant incorporation to improve both processing behavior and dissolution performance.

The drug–excipient compatibility studies using FTIR and DSC confirmed that there were no significant chemical interactions between the drug and selected excipients. This ensured that the observed changes in dissolution behavior were due to physical modifications rather than chemical degradation or interaction. The stability of characteristic peaks in FTIR and absence of major shifts in thermal behavior in DSC indicated that the formulation components were suitable for further development.

The formulation approach using hydrophilic polymers and surfactants showed a marked improvement in drug release compared to the pure drug. The enhancement in dissolution rate can be attributed to multiple mechanisms working simultaneously. The hydrophilic polymers increased water uptake and improved wettability of drug particles, thereby reducing the initial lag phase of dissolution. These polymers also facilitated molecular dispersion of the drug, which reduced crystallinity and increased the surface area available for dissolution.

Surfactants played an important role in reducing interfacial tension between the drug and dissolution medium, leading to improved wetting and dispersion. This prevented aggregation of hydrophobic drug particles and allowed uniform exposure of the drug surface to dissolution media. As a result, the initial dissolution rate was significantly enhanced, especially in the early time points of the study.

XIII. CONCLUSION

The present study titled "Improving Drug Release of Poorly Soluble Drug for Oral Delivery" was successfully carried out with the objective of enhancing the dissolution rate and improving the oral delivery performance of a selected poorly water-soluble drug. The study clearly demonstrated that poor aqueous solubility is a major limiting factor in oral drug bioavailability and that appropriate formulation strategies can effectively overcome this limitation.

The preformulation studies provided a strong scientific basis for formulation development by confirming that the selected drug possesses high crystallinity, strong lipophilicity, poor aqueous solubility, and limited flow properties. These characteristics are typically responsible for slow dissolution and unpredictable absorption behavior. The high partition coefficient confirmed good permeability potential, but the low solubility indicated that dissolution was the rate-limiting step in oral absorption.

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Drug–excipient compatibility studies confirmed that the selected excipients were compatible with the drug and did not show any significant chemical interaction or instability. This ensured that the formulation design was safe and suitable for further development. The micromeritic evaluation also indicated that the pure drug had poor flow properties, which further justified the need for formulation modification to improve handling, processing, and performance characteristics.

The formulation strategies employed in this study, including the use of hydrophilic polymers and surfactants, proved to be effective in enhancing drug release. Hydrophilic polymers improved wettability, increased water penetration, and promoted better dispersion of drug particles in the dissolution medium. This contributed to faster dissolution and reduced lag time. Surfactants further enhanced dissolution by reducing surface tension and preventing aggregation of hydrophobic drug particles, ensuring uniform exposure of the drug surface to the dissolution medium.

The in-vitro dissolution studies confirmed a significant improvement in drug release from the formulated systems compared to the pure drug. The optimized formulation showed higher cumulative drug release, faster dissolution rate, and improved dissolution efficiency. This improvement can be attributed to increased surface area, reduced crystallinity, improved wettability, and better molecular dispersion of the drug within the carrier system.

Stability studies indicated that the optimized formulation remained physically and chemically stable under both normal and accelerated storage conditions. There were no significant changes observed in appearance, drug content, or dissolution profile, suggesting that the formulation is robust and suitable for further development.

XIV. FUTURE SCOPE

The present study clearly demonstrates that improvement in dissolution behavior of poorly water-soluble drugs can be successfully achieved through suitable formulation strategies. However, this area of research has wide potential for further development and optimization in order to achieve better therapeutic performance, scalability, and clinical applicability.

In future research, the formulation can be further optimized by exploring advanced solubility enhancement technologies such as nanotechnology-based drug delivery systems. Nanocrystals, nanosuspensions, and solid lipid nanoparticles can be investigated to further increase surface area and improve saturation solubility, which may result in even faster dissolution and enhanced oral bioavailability.

Future studies may also focus on the development of combination approaches, where multiple techniques such as solid dispersion, surfactant systems, and lipid-based carriers are integrated into a single formulation. Such hybrid systems can provide synergistic effects by simultaneously improving wettability, reducing crystallinity, and enhancing drug solubilization in gastrointestinal fluids.

The incorporation of novel polymeric materials and smart excipients can also be explored. Stimuli-responsive polymers, mucoadhesive agents, and permeability enhancers may help in improving not only dissolution but also intestinal absorption and residence time, leading to improved overall bioavailability.

In vivo pharmacokinetic studies represent an important future direction. Although in-vitro dissolution results indicate improved drug release, in vivo studies are essential to confirm actual improvement in absorption, plasma concentration, and therapeutic efficacy. Correlation between in-vitro dissolution and in-vivo performance (IVIVC) can be established for better prediction of clinical outcomes.

Scale-up and industrial feasibility studies are also important for future development. The optimized formulation should be evaluated for large-scale manufacturing using cost-effective and reproducible methods. Stability under long-term storage conditions, packaging compatibility, and regulatory requirements should also be assessed for commercialization potential.

Future research may also focus on the application of artificial intelligence and machine learning in formulation design. Predictive modeling can help in selecting optimal excipients, polymer ratios, and processing conditions, thereby reducing trial-and-error experimentation and improving development efficiency.

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Additionally, patient-centered formulation development can be explored, including taste masking, dosage form modification, and controlled release systems to improve patient compliance, especially for chronic therapies requiring long-term administration.

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