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Design and Evaluation of Nanoparticle Formulations for Improved Drug Bioavailability

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ABSTRACT

Bioavailability is an important component in the effectiveness of oral medication formulations because it determines the amount and pace at which a drug reaches its target site of action. Poor solubility and absorption are significant hurdles to the development of many promising medication candidates. Nanotechnology, namely nanoparticle-based medicine delivery systems, has emerged as a viable answer to these issues. This study investigates the use of nanotechnology to improve drug solubility, stability, and bioavailability via several nanoparticle formulations, including lipid nanoparticles, magnetic nanoparticles, and polymeric nanoparticles. These nanocarriers not only improve drug solubility, but also provide controlled and prolonged drug release, preserve pharmaceuticals from degradation, and allow for targeted distribution to specific areas in the body, thereby reducing adverse effects. Furthermore, the integration of artificial intelligence (AI) and computational tools has improved nanoparticle design, allowing for the development of tailored therapeutics. The paper focuses on major advances in nanotechnology and its role in altering drug delivery systems, with promising methods for increasing the bioavailability of poorly soluble medicines. Despite advancements, difficulties like as scalability, regulatory constraints, and long-term biocompatibility must be addressed to ensure successful clinical translation

Keywords: *Bioavailability, Nanotechnology, Drug Delivery Systems, Nanoparticles, Lipid Nanoparticles, Magnetic Nanoparticles.*

1. INTRODUCTION

The degree and speed at which the active component (drug or metabolite) enters the bloodstream and reaches the site of action is known as bioavailability [1]. The characteristics of the dosage form, which are partially influenced by its design and manufacturing, greatly influence a drug's bioavailability. Determining whether pharmacological formulations are similar is crucial because variations in bioavailability among formulations of a particular medicine can have therapeutic implications [2].

The majority of medications are taken orally because it is the most convenient for patients receiving long-term care and because stable and easily produced oral formulations are frequently available. The achievement of adequate systemic exposure (plasma or blood concentrations or area under the plasma or blood concentration versus time curve) following oral dosing in animal models is a common requirement during the drug discovery process for a candidate compound meant to be developed into an oral administered drug. Even if a substance has strong effects on the pharmacologic target in vitro, its favorable pharmacologic effects may not be achieved if it is poorly absorbed and plasma concentrations are low after an oral dose. In addition to achieving the intended pharmacologic impact, achieving adequate systemic absorption is crucial for clinical and financial reasons that optimize oral bioavailability. There is more intersubject variability in plasma concentrations when oral bioavailability is poor. A examination of clinical data for 100 medications made this very evident, showing a significant inverse link between the intersubject variability (%CV) in bioavailability and the degree of oral bioavailability [3]. Drug effects, both intended and unwanted, are less well controlled when intersubject variability in bioavailability rises. On the other hand, one medication may have a therapeutic benefit over another for a given indication if its dose versus exposure versus effect characteristics are steady and predictable. Low oral bioavailability also has the practical drawback of wasting a large portion of the medication material that never enters the systemic circulation, which is particularly detrimental for expensive pharmacological compounds. The pharmacologic and adverse effects of the metabolites that are produced must also be taken into account if a drug has low bioavailability as a result of substantial presystemic metabolism. For these reasons, when it comes to drug research and discovery, the goal is to attain the highest

possible oral bioavailability.

Drug discovery paradigms have changed to include the optimization of oral bioavailability (as well as other pharmacokinetic [PK] attributes) in the drug discovery process as part of lead optimization, rather than addressing this issue later in development, due to the high cost of failure in late-stage development. Pharmaceutical research and development has often included evaluating and iteratively improving chemical characteristics to achieve optimal oral bioavailability in humans. The design components and screening techniques that are currently often applied in the oral drug development and candidate identification process are reviewed in this study. The percentage of developmental compounds that fail to become medications because of poor PK or bioavailability qualities has probably decreased as a result of the early use of drug developability criteria in the candidate selection process [4].

The increased focus on activity screening of new compounds using high throughput in vitro assays, such as binding affinity or enzyme inhibition, tends to steer compound synthesis toward properties that favor increased target interaction but are not favorable with regard to oral bioavailability. This is one of the main challenges currently observed in drug discovery. Molecular weight (MW) and lipophilicity have both steadily increased over the past few decades, according to analyses of the characteristics of lead compounds and recently released medications made by different pharmaceutical corporations [5]. As a result, it is becoming more frequent for compounds that exhibit strong in vitro activity and are recognized as leads to also exhibit poor water solubility. According to estimates, 30% of novel compounds at one pharmaceutical business had solubility ≤5 μg/mL and 40% had water solubility ≤50 μg/mL. Oral absorption can undoubtedly be restricted by poor water solubility, particularly if the formulation is not well considered. Addressing the oral transport of poorly water-soluble compounds, particularly assessing the impact of formulation on bioavailability, is becoming more and more crucial in drug discovery and candidate selection. Formulating chemicals in the discovery stage, especially those that are poorly soluble in water, is the subject of this article. A summary of the choices for choosing dosage vehicles and possibly formulations that enable bioavailability is provided.

The review study has 5 sections: In section I, bioavailability was discussed in medication development in terms of absorption and efficacy. Section II discusses nanotechnology's drug design revolution. Section III presents the Nanoparticles improve drug bioavailability by solubility, controlled release, degradation prevention, and targeted administration. Section IV analyzes studies on solubilization and targeting to increase medication absorption. Final section V discusses how nanotechnology can increase bioavailability and medication delivery, especially for oral formulations. Nanoparticles like MNPs improve solubility, stability, and targeting.

2. NANOTECHNOLOGY IN DRUG DESIGN

A. Harnessing Nanotechnology: Enhancing Drug Solubility and Delivery

Nanotechnology solved medicine solubility and bioavailability problems, revolutionizing drug design. It allows nanoscale manipulation of materials to create drug delivery systems that circumvent biological barriers, improving therapeutic outcomes. Traditional formulations struggle with poorly water-soluble medicines' solubility, resulting in inadequate bioavailability and efficacy. Nanotechnology reduces particle size, increases surface area, and improves biological fluid medication solubility. Hydrophobic pharmaceuticals are protected against degradation and improved solubility and stability by liposomes, polymeric nanoparticles, and dendrimers [6]. Nanocarriers can also transport tailored drugs, minimizing systemic adverse effects and improving cancer treatment [7]. Nanotechnology allows theranostic systems to deliver drugs and monitor them in real time, improving tailored therapy [8]. Studies have shown that nanocarriers increase therapeutic absorption and target specific body locations, including oral anticancer drug delivery [9]. Nanotechnology will improve solubility, stability, and targeting, making drugs safer and more effective.

B. Engineering Magnetic Nanoparticles for Enhanced Solubility and Targeted Delivery in the GI Tract

Magnetic particles (MNPs) are a novel way to improve drug solubility and targeted delivery in the GI tract. Drug delivery techniques benefit from these nanoparticles, which have magnetic cores like iron oxide and biocompatible coatings like polymers or lipids [10]. MNPs can be controlled and accumulated at specific body areas using external magnetic fields due to their magnetic characteristics. This enhances medication solubility and targets distribution to the GI tract, where pH and diverse biological conditions often limit drug absorption.

- **Enhancing Drug Solubility Using MNPs**

Increased solubility is one of MNPs' main drug delivery benefits. MNPs' tiny size and huge surface area help poorly soluble medicines disperse and dissolve in water. A study found that PLA-HA/Fe3O4 MNPs loaded with curcumin improved GI medication solubility. This formulation increased curcumin's bioavailability, which is low due to its poor solubility, to treat colorectal cancer [11]. Another study found that CS-g-PNVCL-coated Fe3O4@SiO2 core-shell MNPs might increase solubility, therapeutic efficacy, and treatment dose [12]. These findings highlight MNPs' involvement in improving solubility, bioavailability, and GI tract therapeutic efficacy.

- **GI Tract Targeted Delivery**

Magnetic nanoparticles (MNPs) improve drug solubility for GI tract distribution. These nanoparticles diffuse hydrophobic medicines, making them wettable and preventing agglomeration. A study with curcumin showed that MNPs increased its solubility and therapeutic efficacy against breast cancer [13]. Functionalization with biocompatible polymers like chitosan and sodium alginate increases stability and controls release patterns. Hyperthermia-induced amorphization of a model medication employing superparamagnetic MNPs shows that MNPs can amorphize poorly soluble medicines [14]. In magnetic ferrite nanoparticles coated with bovine serum albumin and glycine polymers, MNPs control curcumin release to maintain therapeutic levels in the GI tract [15]. Docetaxel co-loaded on magnetic nanostructured lipid carriers improves lung cancer treatment solubility and efficacy [16]. MNPs can improve solubility and bioavailability of poorly soluble medicines, suggesting solutions for current drug delivery systems.

- **MNPs in Drug Delivery: Engineering Considerations**

Magnetic nanoparticles (MNPs) must be engineered to optimise surface characteristics, biocompatibility, and drug loading efficiency for drug delivery. The modification of magnetic iron oxide nanoparticles for breast cancer detection and treatment shows that biocompatible polymers and proteins are needed to stabilize and minimize toxicity [17]. Self-unfolding foils with MNPs for oral drug delivery use targeting ligands like antibodies or peptides to deliver drugs to specific cells without off-target effects [18]. A magnetic scaffold investigation found that mathematical modeling predicts MNP-biological environment interactions, addressing issues such inhomogeneous drug distribution and burst release [19]. As in hybrid nanoparticles that optimize blood flow in stenosed arteries, hemodynamic factors can improve medication delivery [20]. Studies on erythrocyte-encapsulated superparamagnetic iron oxide nanoparticles show promise for improving therapeutic outcomes [21]. Dual-responsive MNP systems that respond to pH and temperature are also being developed for controlled drug release. Another novel technique is to integrate magnetic characteristics with other therapeutic methods, such as hyperthermia, as shown in magnetic nickel ferrite nanoparticles for drug transport and treatment [22]. Finally, improving MNP adherence to atherosclerotic plaques under magnetic and ultrasonic fields shows that MNPs must interact with biological tissues to be biocompatible and safe [23].

3. MECHANISMS FOR IMPROVING DRUG BIOAVAILABILITY

Drug bioavailability is the percentage of an administered medicine that enters the systemic circulation as active. Drug bioavailability, especially for poorly soluble, degradable, or poorly absorbed medicines, is a major difficulty in pharmaceutical drug development [24]. To solve these obstacles, nanoparticle-based medication delivery technologies seem promising. Nanoparticles increase medication bioavailability through these main mechanisms:

A. Drug Solubility Improvement

Drug solubility, especially hydrophobic or low water solubility medicines, is a major cause of poor bioavailability. Nanoparticles can greatly improve dissolution surface area by shrinking drug particles to nanometers. A larger surface area helps the medication dissolve faster in gastrointestinal fluids, enhancing absorption [25]. Nanoparticles can produce solid dispersions or drug-polymer complexes, improving the solubility of weakly soluble substances. Solubilizing hydrophobic medicines with solid lipid nanoparticles, liposomes, and nanocrystals is frequent. These nanoparticles improve solubility and protect pharmaceuticals from environmental deterioration, improving stability and bioavailability. Lipid-based nanoparticles or nanocrystals can dissolve poorly water-soluble medicines faster and more completely in the gastrointestinal tract. Once medications enter systemic circulation, they are more active and easier to absorb.

B. Controlled & sustained release

Many medications need controlled and sustained release formulations to improve bioavailability. Encapsulating medications in nanoparticles controls their release into the body. This means the drug is released steadily over time, rather than rapidly, which may cause high peak concentrations and fast elimination [26]. This continuous release maintains a steady plasma medication concentration, improving bioavailability and lowering administration frequency. Polymeric nanoparticles, lipid-core micelles, and hydrogels release drug payloads slowly, prolonging therapeutic effects and limiting adverse effects [27]. Nanoparticles can release medications that need a steady blood concentration in a controlled manner that matches the body's needs. Nanoparticle formulations' prolonged release minimizes peak drug concentration-related side effects, improving bioavailability.

C. Degradation Prevention

Many medications degrade in the gastrointestinal tract due to acidity or enzymatic action. Some medicines also undergo substantial liver first-pass metabolism, decreasing systemic availability. Encapsulating pharmaceuticals in nanoparticle carriers protects them against digestive enzymes and acidic environments [28]. Liposomes, polymeric micelles, and solid lipid nanoparticles protect pharmaceuticals against premature degradation. These particles help prevent the enzymatic degradation of sensitive medications including peptides, proteins, and nucleic acids, which would otherwise be destroyed

before they could work. Nanoparticle-encapsulated medications are less likely to be broken down by gastrointestinal enzymes, and the nanocarrier avoids drug loss before it reaches the bloodstream. This degradation protection increases the bioavailability of these medications, ensuring that more active molecule reaches the systemic circulation.

D. Specific Delivery and Absorption

One of nanoparticle-based formulations' biggest advantages is targeted medication delivery. Drugs delivered nonspecifically by traditional drug delivery systems can have off-target effects and lower therapeutic efficacy. Drug delivery is more precise when nanoparticles target specific cells, tissues, or organs. Nanoparticles can be functionalized with ligands (e.g., antibodies, peptides) that attach to tumor cell receptors, making this targeted delivery technique crucial in cancer. Nanoparticles transport the medicine directly to the target site, enhancing drug concentration and reducing systemic exposure, which can cause side effects [29]. Nanoparticles also boost medicine absorption across biological barriers. The blood-brain barrier (BBB), which shields the brain from hazardous chemicals, makes delivering neurological illness medications difficult. Lipid or polymer nanoparticles can cross the BBB, improving brain-disease medication bioavailability. Nanoparticles also improve gastrointestinal epithelial medication absorption. This applies to hydrophobic or large-molecular-size medications that are poorly absorbed. Nanoparticles can help these medications cross the intestinal wall into the bloodstream, enhancing oral bioavailability.

4. EVALUATION OF NANOPARTICLE FORMULATIONS

Modern pharmaceutical research relies on nanoparticle-based drug delivery technologies to improve the solubility and bioavailability of water-insoluble drugs. Poor solubility impedes drug development; 40% of new drugs have low water solubility, reducing absorption, bioavailability, and therapeutic efficacy. By increasing surface area, dissolving rates, and medication targeting and release, nanoparticle-based systems can solve these issues [30]. Researchers intend to reduce dose, remove side effects, and maximize the therapeutic potential of poorly soluble drugs using nanoparticle compositions.

Below is a review table summarizing the results of some previous studies.

Table 1: Review Table

Author(s) and Year	Drug(s) Name	Methodology	Findings
Kapoor et al. (2024)	Nanoparticle-based drug delivery systems	Review on the integration of AI in the design and formulation of nanoparticles (NPs) for drug delivery, using machine learning, neural networks, and optimization algorithms.	Nanoparticle-based systems enhance drug bioavailability, improve targeted drug delivery, and decrease side effects. AI plays a critical role in customizing NP size, surface chemistry, and drug release profiles, enabling personalized treatments.
Yu et al. (2025)	BCS IV drugs (general, no specific drug mentioned)	Preclinical study on amorphous nanoparticle (ANP) formulation, using solvent/antisolvent precipitation, organic solvent removal, and freeze-drying (FD) for oral solution.	45% DL ANP formulation showed better pharmacokinetics in canines and higher Cmax and AUC in humans. Scaling up was challenging, but the ANP formulation outperformed ASD approach in terms of bioavailability and stability.
Zhuo et al. (2024)	Drugs with solubility/bioavailability issues	Review on the impact of nanotechnology (including magnetic nanoparticles) and AI in overcoming biological variability and improving drug solubility and bioavailability.	Nanotechnology and AI have transformed drug delivery systems, helping overcome solubility and absorption challenges. Integration of AI in the formulation process holds promise for personalized therapies and more effective treatments.
Gangavarapu et al. (2024)	BCS II and IV drugs (e.g., hydrophobic drugs)	Review on lipid nanoparticles (LNPs), including solid lipid nanoparticles (SLN) and nanostructured lipid carriers (NLC), for enhancing	LNPs significantly enhance the bioavailability of poorly permeable drugs, improving their gastrointestinal absorption and solubilization. Computational tools can optimize

		bioavailability of biopharmaceutics.	LNP behavior for improved therapeutic outcomes.
Maurya et al. (2024)	Oral medications (general, no specific drug mentioned)	Review on conventional and novel drug delivery techniques (e.g., cyclodextrins, micelles, nanocarriers, lipid-based carriers) for improving oral bioavailability.	Highlighted advancements in oral drug delivery systems to overcome solubility, permeability, and stability challenges. Focus on enhancing bioavailability through improved pharmaceutical technologies and novel drug delivery techniques.

5. CONCLUSION

This study emphasizes bioavailability's importance in drug development, especially oral formulations. Nanotechnology can alter medication delivery systems to improve the solubility and absorption of several attractive therapeutic candidates. Drug solubility, stability, and bioavailability can be increased by nanoparticles, particularly magnetic nanoparticles, improving therapeutic outcomes and lowering side effects. Engineering nanoparticles for controlled and targeted medication distribution and degradation protection provides a solid framework for overcoming numerous drug development challenges. AI and computational techniques improve medication formulation precision and customisation, enabling more tailored and effective therapies. As research continues, nanotechnology and revolutionary drug delivery technologies will transform pharmaceutical development, giving patients with solubility and bioavailability issues hope. These promising technologies must overcome scaling and regulatory approval issues to become widely used in clinical practice.

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