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SOLID DISPERSION TECHNOLOGY IN TABLET FORMULATION: PRINCIPLES, PREPARATION METHODS, AND PHARMACEUTICAL APPLICATIONS

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ABSTRACT

Poor aqueous solubility limits the oral bioavailability of many active pharmaceutical ingredients (APIs). Solid dispersion technology has emerged as one of the most successful formulation strategies to improve dissolution rate and oral absorption of poorly water-soluble drugs. In tablet formulations, solid dispersions combine enhanced drug release with the convenience, stability, and patient acceptance of oral solid dosage forms. This manuscript reviews the principles, classification, carriers, preparation methods, characterization techniques, tablet formulation strategies, pharmaceutical applications, commercial products, challenges, and future prospects of solid dispersion technology.

KEYWORDS: Solid dispersion, tablet formulation, bioavailability, dissolution enhancement, amorphous solid dispersion, hydrophilic polymers.

1. INTRODUCTION

Oral drug delivery remains the most preferred and widely accepted route for systemic drug administration due to its convenience, non-invasive nature, cost-effectiveness, ease of manufacturing, and high patient compliance. Tablets and capsules constitute the majority of pharmaceutical products available in the market because they offer precise dosing, good stability, portability, and ease of administration. Despite these advantages, the successful oral delivery of many therapeutic agents is significantly limited by their poor aqueous solubility.[1] Drug dissolution is the first and one of the

most critical steps in the absorption process for orally administered medications. According to the Biopharmaceutical Classification System (BCS), drugs belonging to Class II (low solubility, high permeability) and Class IV (low solubility, low permeability) often exhibit dissolution-limited absorption, resulting in poor and highly variable oral bioavailability. It has been estimated that approximately 40–70% of newly discovered chemical entities (NCEs) and nearly 90% of compounds emerging from modern drug discovery programs possess poor aqueous solubility.

Consequently, improving the dissolution characteristics of these poorly water-soluble drugs has become a major challenge in pharmaceutical formulation research and development.[2]

Several formulation approaches have been investigated to overcome poor solubility, including particle size reduction, micronization, nanocrystal technology, salt formation, cyclodextrin complexation, lipid-based formulations, co-crystallization, and solid dispersion technology. Among these strategies, solid dispersion (SD) technology has gained considerable attention because of its simplicity, versatility, and ability to significantly enhance drug dissolution and oral bioavailability without altering the chemical structure of the active pharmaceutical ingredient (API). The concept of solid dispersion was first introduced by Sekiguchi and Obi in 1961, who demonstrated that poorly soluble drugs dispersed within water-soluble carriers exhibited remarkably faster dissolution compared with the pure crystalline drug. Their pioneering work laid the foundation for the development of modern solid dispersion systems, which have since evolved into one of the most promising techniques for improving the performance of poorly soluble drugs.[3]

Solid dispersions are defined as systems in which one or more active pharmaceutical ingredients are molecularly dispersed or finely distributed within an inert hydrophilic carrier in the solid state. The enhanced dissolution observed in these systems is attributed to several mechanisms, including reduction in drug particle size, transformation of the drug from a crystalline to an amorphous state, improved wettability, increased porosity, enhanced surface area, and prevention of drug aggregation. Hydrophilic polymers such as polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), hydroxypropyl methylcellulose (HPMC), Soluplus®, and Poloxamer 188 are commonly employed as carriers because they facilitate rapid water penetration and stabilize the amorphous drug during storage.[4]

In recent years, solid dispersion technology has been successfully integrated into tablet dosage forms, combining the advantages of improved dissolution with the convenience, stability, and patient acceptability of conventional tablets. The prepared solid dispersions are blended with suitable pharmaceutical excipients and compressed using standard tableting techniques, making the process readily adaptable to industrial manufacturing. Furthermore, advances in hot-melt extrusion, spray drying, freeze drying, and continuous manufacturing technologies have significantly expanded the commercial feasibility of solid dispersion-based tablets. Several marketed pharmaceutical products now employ amorphous solid dispersion technology to enhance the bioavailability of poorly soluble drugs, highlighting its growing importance in modern drug development.[5]

This review comprehensively discusses the principles, mechanisms, preparation methods, characterization techniques, formulation considerations, evaluation parameters, pharmaceutical applications, recent advances, challenges, and future prospects of solid dispersion technology in tablet formulation. By summarizing current scientific knowledge and industrial developments, this review aims to provide researchers, formulation scientists, and pharmaceutical professionals with a detailed understanding of the role of solid dispersion systems in improving oral drug delivery and enhancing the therapeutic performance of poorly water-soluble drugs.[6]

2. Drug Solubility and BCS

The Biopharmaceutical Classification System (BCS) is a scientific framework developed to classify drug substances based on their aqueous solubility and intestinal permeability, two critical factors that influence the oral absorption and bioavailability of pharmaceutical compounds. The BCS was introduced by Amidon et al. in 1995 and has since been widely adopted by regulatory agencies such as the United States Food and Drug Administration (USFDA), the European Medicines Agency (EMA), and the World Health Organization (WHO). This classification system serves as an important tool in pharmaceutical research and development, enabling formulation scientists to predict the in vivo performance of orally administered drugs and select appropriate formulation strategies to enhance drug delivery.[7]

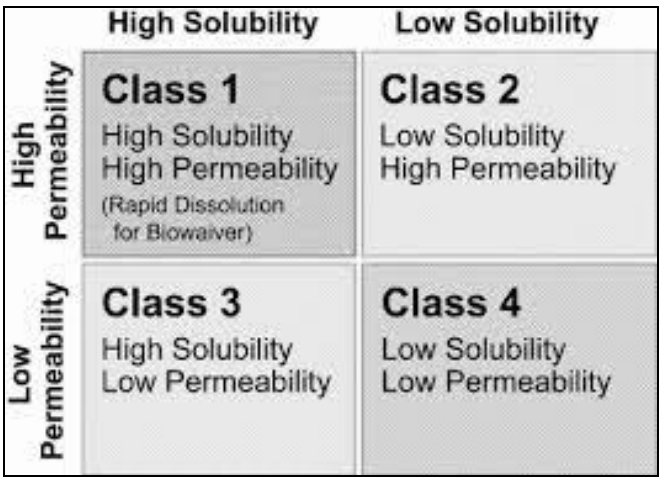

Fig: Biopharmaceutical Classification System (BCS).

According to the BCS, drugs are categorized into four classes based on their solubility and permeability characteristics. Class I drugs possess high solubility and high permeability, resulting in rapid dissolution and efficient absorption from the gastrointestinal tract. These drugs generally exhibit excellent oral bioavailability and require minimal formulation intervention. Examples include metoprolol and paracetamol. Class II drugs are characterized by low solubility but high permeability. Although these drugs readily cross biological membranes, their poor aqueous solubility limits their dissolution in gastrointestinal fluids, making dissolution the rate-limiting step for absorption. Consequently, formulation approaches aimed at improving dissolution are essential for enhancing their bioavailability. Representative examples include celecoxib, carbamazepine, ibuprofen, ketoconazole, and itraconazole.[8]

Class III drugs exhibit high solubility but low permeability. These drugs dissolve rapidly in gastrointestinal fluids; however, their absorption is restricted by poor membrane permeability rather than dissolution. Therefore, formulation strategies for Class III drugs generally focus on improving intestinal permeability rather than solubility. Examples include cimetidine and atenolol. Finally, Class IV drugs possess both low solubility and low permeability, making them the most challenging compounds for oral drug delivery. These drugs often demonstrate poor and highly variable bioavailability because both dissolution and membrane transport limit absorption. Examples include hydrochlorothiazide and furosemide.[9]

Among these categories, solid dispersion technology is particularly beneficial for BCS Class II and Class IV drugs, where poor aqueous solubility is the primary barrier to effective oral absorption. In these drugs, the dissolution rate governs the amount of drug available for permeation across the intestinal membrane. Solid dispersion technology

enhances dissolution by dispersing poorly soluble drug molecules within hydrophilic carriers such as polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), Soluplus®, and Poloxamer 188. These carriers improve the wettability of drug particles, reduce particle size to the molecular level, convert crystalline drugs into amorphous forms, and prevent particle aggregation. As a result, the drug dissolves more rapidly in gastrointestinal fluids, producing higher concentrations of dissolved drug available for absorption.[10]

The integration of solid dispersion technology into tablet formulations has significantly improved the oral bioavailability of numerous poorly soluble drugs. Modern manufacturing techniques such as hot-melt extrusion, spray drying, solvent evaporation, and freeze drying facilitate the production of stable amorphous solid dispersions that can be compressed into tablets using conventional pharmaceutical equipment. These formulations provide enhanced dissolution profiles, faster onset of therapeutic action, reduced dose variability, and improved patient compliance. The Biopharmaceutical Classification System provides a valuable scientific basis for selecting formulation strategies according to the physicochemical properties of drug molecules. For BCS Class II and Class IV drugs, where poor aqueous solubility limits oral absorption, solid dispersion technology has emerged as one of the most effective and commercially successful approaches for improving dissolution rate and bioavailability. Consequently, the BCS continues to guide pharmaceutical scientists in the rational design and optimization of solid dispersion-based tablet formulations for poorly water-soluble drugs.[11]

3. Principles and Mechanisms

The effectiveness of solid dispersion technology in enhancing the oral bioavailability of poorly water-soluble drugs is primarily attributed to its ability to improve the dissolution rate, which is often the rate-limiting step in drug absorption.

The enhanced dissolution achieved through solid dispersion systems results from several complementary mechanisms, including particle size reduction, conversion of the crystalline drug into an amorphous form, improved wettability, increased porosity, prevention of drug aggregation, and molecular dispersion within hydrophilic carriers. These mechanisms work synergistically to increase the amount of drug dissolved in gastrointestinal fluids, thereby improving its absorption and therapeutic efficacy. One of the primary mechanisms responsible for dissolution enhancement is particle size reduction. According to the Noyes–Whitney equation, the dissolution rate of a drug is directly proportional to its surface area. Conventional techniques such as micronization reduce particle size to the micrometer range; however, solid dispersion technology can disperse drug molecules at the molecular or nanometer level within a carrier matrix. This dramatic reduction in particle size substantially increases the available surface area for contact with dissolution media, leading to a faster dissolution rate. Since the drug exists as extremely fine particles or molecularly dispersed entities, dissolution occurs much more rapidly than with coarse crystalline powders.[12]

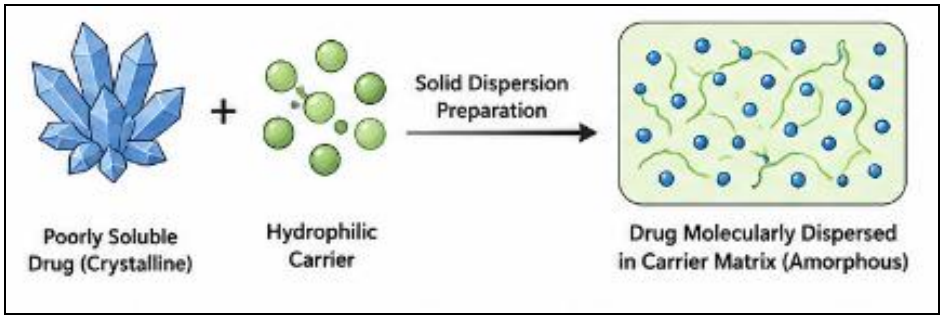

Fig: Principles and Mechanisms.

Another important mechanism is the conversion of the drug from a crystalline to an amorphous state. Crystalline drugs possess highly ordered molecular arrangements stabilized by strong intermolecular forces, requiring considerable energy to dissolve. In contrast, amorphous drugs lack long-range molecular order and possess higher free energy and molecular mobility. Consequently, the amorphous form exhibits significantly greater apparent solubility and faster dissolution than its crystalline counterpart. Hydrophilic polymers present in solid dispersions stabilize the amorphous drug during storage by inhibiting molecular rearrangement and recrystallization, thereby maintaining enhanced dissolution characteristics. Improved wettability also plays a crucial role in increasing drug dissolution. Poorly water-soluble drugs generally exhibit hydrophobic surfaces that resist wetting by gastrointestinal fluids, delaying dissolution.

Hydrophilic carriers such as polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), Soluplus®, and Poloxamer 188 readily absorb water and facilitate rapid penetration of dissolution media around drug particles. The improved wetting reduces the interfacial tension between the drug surface and the aqueous medium, promoting rapid dissolution.[13]

Solid dispersion systems also exhibit increased porosity, which further enhances dissolution. During preparation methods such as spray drying, freeze drying, or solvent evaporation, porous matrices are generated. These porous structures permit rapid penetration of dissolution media, increasing the contact area between water and the dispersed drug. Greater porosity accelerates solvent diffusion into the matrix and facilitates rapid drug release. Another important mechanism involves the prevention of drug particle aggregation. Poorly soluble drugs frequently tend to aggregate due to their hydrophobic nature, thereby reducing the effective surface area available for dissolution. In solid dispersions, hydrophilic polymers surround and separate individual drug particles, preventing their aggregation during manufacturing, storage, and dissolution. This stabilization ensures that the drug remains uniformly dispersed and readily accessible to dissolution media. Perhaps the most significant mechanism is the molecular dispersion of drug molecules within hydrophilic carriers. In an ideal solid dispersion, drug molecules are homogeneously dispersed at the molecular level throughout the polymer matrix, eliminating large crystalline domains. This intimate mixing significantly shortens the diffusion pathway for drug molecules and enables immediate interaction with gastrointestinal fluids upon tablet disintegration. The hydrophilic carrier rapidly dissolves, releasing drug molecules into solution and often generating a transient supersaturated state that enhances intestinal absorption.[14]

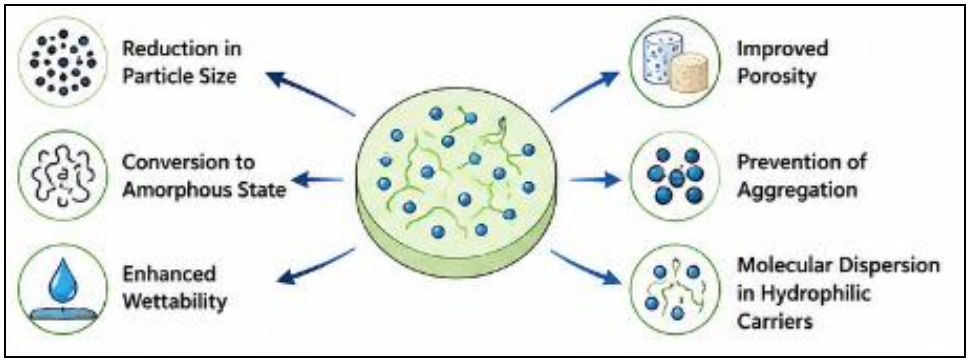

Fig: Solid dispersion systems.

Collectively, these mechanisms contribute to the superior performance of solid dispersion-based formulations. By simultaneously increasing surface area, reducing crystallinity, enhancing wettability and porosity, preventing

aggregation, and achieving molecular-level drug dispersion, solid dispersion technology has become one of the most effective formulation strategies for improving the dissolution, oral bioavailability, and therapeutic performance of poorly water-soluble drugs, particularly those belonging to BCS Class II and Class IV categories.[15]

7. Tablet Formulation

Solid dispersion technology is one of the most effective formulation approaches for improving the dissolution and oral bioavailability of poorly water-soluble drugs. However, the prepared solid dispersion alone is not suitable for direct administration because it often exhibits poor flowability, inadequate compressibility, and difficulty in handling during large-scale manufacturing. Therefore, the solid dispersion is converted into a conventional tablet dosage form by blending it with suitable pharmaceutical excipients and subsequently compressing the blend into tablets using direct compression or granulation techniques. The selection of appropriate excipients and careful evaluation of tablet quality attributes are essential to ensure the production of stable, effective, and patient-friendly dosage forms. After preparation by methods such as fusion (melting), solvent evaporation, spray drying, freeze drying, or hot-melt extrusion, the solid dispersion is dried, pulverized, and passed through a suitable sieve to obtain uniform particle size. The resulting powder is then mixed with excipients that perform specific functions during manufacturing and drug release.[16]

One of the most commonly used excipients is microcrystalline cellulose (MCC), which serves as a filler, dry binder, and compression aid. MCC possesses excellent compressibility and helps produce tablets with sufficient mechanical strength even under relatively low compression pressure. In addition, it improves the flow properties of the powder blend and contributes to rapid tablet disintegration because of its porous structure. Lactose is another widely used diluent or filler incorporated to increase the bulk of the formulation and improve tablet weight uniformity. Since many drugs are administered in very small quantities, lactose provides the necessary tablet size for accurate handling and manufacturing. It also exhibits good compatibility with most pharmaceutical ingredients and contributes to improved tablet hardness.[17]

To facilitate rapid tablet breakup after administration, superdisintegrants are incorporated into the formulation. Crospovidone acts primarily through capillary action (wicking), rapidly drawing water into the tablet matrix and promoting disintegration without extensive swelling. Sodium starch glycolate (SSG) functions by absorbing water and swelling many times its original volume, generating internal pressure that causes the tablet to disintegrate quickly. Rapid disintegration exposes the solid dispersion to gastrointestinal fluids, allowing the drug to dissolve more rapidly and enhancing its absorption. The formulation also requires lubricants and glidants to ensure efficient tablet manufacturing. Magnesium stearate is the most widely used lubricant because it reduces friction between the powder and the punches and dies during compression, facilitating smooth tablet ejection and minimizing sticking. However, excessive magnesium stearate may coat drug particles and decrease dissolution; therefore, it is generally used in concentrations below 1%. Talc acts primarily as a glidant and anti-adherent. It improves powder flow, reduces interparticle friction, prevents sticking of powder to compression tooling, and contributes to uniform die filling during tablet production.[18]

After blending all formulation components, tablets may be prepared using direct compression, wet granulation, or dry granulation. Direct compression is preferred for many solid dispersion formulations because it is simple, economical, and minimizes exposure of the amorphous drug to heat and moisture, thereby preserving its physical stability. However, if the powder blend exhibits poor flowability or inadequate compressibility, granulation techniques may be

employed to improve handling and ensure uniform tablet quality. The quality of solid dispersion-based tablets is assessed through several Critical Quality Attributes (CQAs), which determine their performance, safety, and manufacturability. Flowability is the ability of the powder blend to flow uniformly into the tablet die. It is evaluated using parameters such as angle of repose, bulk density, tapped density, Carr's compressibility index, and Hausner ratio. Good flowability ensures uniform die filling and consistent tablet weight. Compressibility refers to the ability of the powder to form coherent tablets under compression pressure. Good compressibility produces tablets with adequate hardness while minimizing defects such as capping and lamination.[19]

Hardness measures the mechanical strength of tablets and indicates their ability to withstand handling, packaging, transportation, and storage without breaking. Tablets should possess sufficient hardness while still allowing rapid disintegration after administration.

Friability evaluates the tablet's resistance to abrasion and mechanical stress. It is commonly determined using a friabilator, and pharmacopeial standards generally specify a weight loss of less than 1%, indicating acceptable mechanical durability. Disintegration time is a critical parameter for immediate-release solid dispersion tablets.

It measures the time required for the tablet to break into smaller particles when exposed to physiological fluids. Rapid disintegration facilitates faster dissolution of the incorporated solid dispersion and enhances drug availability. Drug content uniformity ensures that every tablet contains the intended amount of active pharmaceutical ingredient within pharmacopeial limits. Uniform drug distribution is particularly important in solid dispersion formulations because the drug is often present in an amorphous or molecularly dispersed state. Among all evaluation parameters, dissolution testing is considered the most important quality attribute. Dissolution studies determine the rate and extent of drug release from the tablet in simulated gastrointestinal fluids. Since the primary objective of solid dispersion technology is to improve dissolution and oral bioavailability, a rapid and reproducible dissolution profile confirms the success of the formulation. Enhanced dissolution generally results in improved absorption, reduced variability in therapeutic response, and increased bioavailability of poorly water-soluble drugs.[20]

9. Pharmaceutical Applications

Solid dispersion technology has become one of the most effective formulation approaches for enhancing the oral delivery of poorly water-soluble drugs. By improving drug dissolution and apparent solubility, solid dispersion-based tablets have demonstrated significant improvements in oral bioavailability, therapeutic efficacy, and patient compliance. Numerous pharmaceutical compounds belonging to Biopharmaceutical Classification System (BCS) Class II and Class IV have been successfully formulated as solid dispersion-based tablets, making this technology highly relevant in both research and commercial pharmaceutical development.

One of the earliest and most extensively investigated drugs is ibuprofen, a non-steroidal anti-inflammatory drug (NSAID) with poor aqueous solubility. Conventional ibuprofen tablets often exhibit delayed dissolution, especially under low gastric fluid conditions. Formulating ibuprofen as a solid dispersion using hydrophilic carriers such as polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), or hydroxypropyl methylcellulose (HPMC) significantly increases its dissolution rate, leading to faster onset of analgesic and anti-inflammatory action. Enhanced dissolution also improves drug absorption and reduces interpatient variability.[21]

Another important NSAID formulated using solid dispersion technology is celecoxib, a selective cyclooxygenase-2 (COX-2) inhibitor widely used for treating arthritis and pain. Celecoxib exhibits extremely low water solubility, which limits its oral bioavailability. Amorphous solid dispersions prepared with polymers such as Soluplus®, PVP, and HPMC-AS have demonstrated several-fold increases in dissolution rate and systemic drug exposure. Consequently, these formulations provide improved therapeutic efficacy while reducing dose-related variability.

Atorvastatin calcium, a lipid-lowering agent used in the treatment of hypercholesterolemia, also suffers from poor aqueous solubility and extensive first-pass metabolism. Solid dispersion-based tablets prepared using hydrophilic polymers enhance atorvastatin dissolution and increase oral absorption, thereby improving lipid-lowering efficacy. Similar benefits have been reported for glibenclamide, an oral antidiabetic drug, where enhanced dissolution results in faster absorption and more consistent glycemic control. Natural products such as curcumin have also benefited from solid dispersion technology. Although curcumin possesses potent antioxidant, anti-inflammatory, and anticancer properties, its clinical application is limited by extremely poor water solubility and low oral bioavailability. Solid dispersion systems prepared with carriers such as PVP, PEG, and Soluplus markedly increase curcumin dissolution, improve gastrointestinal absorption, and enhance its pharmacological activity.[22]

Among antiepileptic agents, carbamazepine is one of the most extensively studied drugs in solid dispersion research.

Carbamazepine exhibits polymorphism and poor aqueous solubility, leading to variable dissolution and inconsistent therapeutic response. Incorporating carbamazepine into amorphous solid dispersions stabilizes the drug, accelerates dissolution, and improves bioavailability while minimizing polymorphic transformation. Several antifungal drugs have also been successfully formulated using solid dispersion technology. Ketoconazole and itraconazole are highly lipophilic antifungal agents with dissolution-limited absorption. Solid dispersions prepared using polymers and surfactants significantly improve their dissolution profiles, allowing greater drug absorption and enhanced antifungal activity. Similar improvements have been reported for nifedipine, a calcium channel blocker used in hypertension and angina, where rapid dissolution contributes to faster therapeutic action.

In recent years, solid dispersion technology has attracted considerable attention in anticancer drug delivery. Many chemotherapeutic agents, including paclitaxel, docetaxel, sorafenib, erlotinib, gefitinib, dasatinib, and sunitinib, exhibit poor aqueous solubility, limiting their oral bioavailability. Amorphous solid dispersions prepared using advanced polymers and hot-melt extrusion or spray-drying techniques have demonstrated substantial improvements in dissolution, systemic exposure, and therapeutic effectiveness. These formulations also enable dose reduction while maintaining clinical efficacy and minimizing adverse effects. Overall, the pharmaceutical applications of solid dispersion-based tablets continue to expand across diverse therapeutic areas, including analgesics, anti-inflammatory agents, antihyperlipidemic drugs, antidiabetics, antihypertensives, antiepileptics, antifungals, and anticancer agents.

The ability of solid dispersion technology to improve dissolution, enhance oral bioavailability, reduce dose variability, and increase therapeutic effectiveness has made it one of the most promising formulation strategies in modern pharmaceutical development. Ongoing advances in polymer science, manufacturing technologies, and amorphous solid dispersion stabilization are expected to further broaden its application in the formulation of next-generation oral drug delivery systems.[23]

CONCLUSION

Solid dispersion technology has emerged as one of the most promising and widely adopted formulation strategies for overcoming the challenges associated with the oral delivery of poorly water-soluble drugs. With an increasing proportion of newly developed drug candidates exhibiting low aqueous solubility, enhancing dissolution and bioavailability has become a critical objective in pharmaceutical formulation development. Solid dispersion systems effectively address this issue by dispersing drug molecules within hydrophilic carriers, thereby improving drug wettability, reducing particle size, converting crystalline drugs into the more soluble amorphous form, increasing porosity, preventing particle aggregation, and promoting molecular-level dispersion. These combined mechanisms significantly enhance the dissolution rate and, consequently, the oral bioavailability of poorly soluble drugs.

In conclusion, solid dispersion technology represents a highly effective, versatile, and commercially viable platform for enhancing the dissolution, oral bioavailability, and therapeutic performance of poorly water-soluble drugs. Continuous advancements in material science, pharmaceutical engineering, and process optimization are expected to further strengthen its role in the development of next-generation oral drug delivery systems. Consequently, solid dispersion-based tablet formulations will continue to play a pivotal role in improving drug therapy, accelerating pharmaceutical innovation, and expanding the range of clinically effective oral medicines for the treatment of various diseases.

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