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Review Paper

A Comprehensive Review: Solid Dispersion Technology for Enhancement of Gliclazide Solubility and Dissolution

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ABSTRACT

Gliclazide is a second-generation sulfonylurea widely used in the management of Type 2 diabetes mellitus. Despite its proven therapeutic efficacy, its poor aqueous solubility and slow dissolution rate limit its oral bioavailability, resulting in variable drug absorption. As a Biopharmaceutics Classification System (BCS) Class II drug, enhancing the solubility and dissolution of gliclazide is essential for improving its clinical performance. Among the various formulation approaches, solid dispersion technology has emerged as an effective and widely accepted strategy for overcoming poor water solubility. In this technique, gliclazide is dispersed within hydrophilic carriers such as polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), poloxamers, and Soluplus®, leading to improved wettability, reduced crystallinity, increased surface area, and enhanced dissolution rate. Various preparation methods, including fusion, solvent evaporation, spray drying, and hot-melt extrusion, have been successfully employed to develop gliclazide solid dispersions. Characterization techniques such as Fourier-transform infrared spectroscopy (FTIR), differential scanning calorimetry (DSC), powder X-ray diffraction (PXRD), and scanning electron microscopy (SEM) are used to evaluate the physicochemical properties of the formulations. This review summarizes the drug profile of gliclazide, the principles of solid dispersion technology, preparation methods, characterization techniques, advantages, limitations, and future perspectives. Overall, solid dispersion technology offers a promising and practical approach for enhancing the solubility, dissolution rate, oral bioavailability, and therapeutic efficacy of gliclazide.

INTRODUCTION

Oral drug delivery remains the most preferred route of drug administration because of its

convenience, patient compliance, cost-effectiveness, and ease of manufacturing. However, poor aqueous solubility is one of the

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major challenges encountered during the development of oral dosage forms. More than 40% of marketed drugs and nearly 70–90% of newly discovered chemical entities exhibit poor water solubility, resulting in slow dissolution, incomplete absorption, low oral bioavailability, and variable therapeutic response. According to the Biopharmaceutics Classification System (BCS), drugs belonging to Class II possess high membrane permeability but low aqueous solubility, making dissolution the rate-limiting step for their gastrointestinal absorption. Therefore, enhancing the dissolution rate of poorly soluble drugs has become a major focus in modern pharmaceutical formulation research⁽¹⁻³⁾

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and progressive dysfunction of pancreatic β -cells, leading to persistent hyperglycemia. Long-term uncontrolled hyperglycemia contributes to serious complications such as diabetic nephropathy, retinopathy, neuropathy, and cardiovascular diseases. Sulfonylureas remain an important class of oral antidiabetic agents due to their efficacy in stimulating endogenous insulin secretion. Among them, gliclazide is a widely prescribed second-generation sulfonylurea because of its potent hypoglycemic activity, lower incidence of severe hypoglycemia compared with several older sulfonylureas, antioxidant activity, and favorable cardiovascular safety profile⁽⁴⁾

Gliclazide acts by selectively inhibiting ATP-sensitive potassium (KATP) channels located on pancreatic β -cells. Closure of these channels causes membrane depolarization, opening of voltage-dependent calcium channels, influx of calcium ions, and subsequent release of insulin. Besides its insulinotropic effect, gliclazide has been reported to reduce oxidative stress, inhibit platelet aggregation, improve endothelial function, and decrease the progression of diabetic

microvascular complications. These additional pharmacological properties distinguish gliclazide from several other sulfonylurea derivatives and contribute to its widespread clinical use⁽⁴⁾

Despite its therapeutic advantages, gliclazide suffers from poor aqueous solubility, approximately 0.19 mg/mL in water, resulting in slow and incomplete dissolution in gastrointestinal fluids. Because of its low solubility and high permeability, gliclazide is generally classified as a BCS Class II drug. Consequently, its oral absorption largely depends on its dissolution behavior within the gastrointestinal tract. Slow dissolution may produce delayed onset of action, inter-individual variability in plasma drug concentration, reduced bioavailability, and inconsistent glycemic control. Therefore, formulation strategies that improve the dissolution characteristics of gliclazide are expected to enhance its oral absorption and therapeutic efficacy⁽⁴⁻⁵⁾

Several approaches have been explored to improve the solubility and dissolution of gliclazide, including micronization, nanocrystals, nanosuspensions, cyclodextrin inclusion complexes, lipid-based drug delivery systems, self-emulsifying drug delivery systems (SEDDS), liquisolid compacts, co-crystals, amorphous formulations, and solid dispersion technology. Although each technique offers certain advantages, many involve complex manufacturing processes, expensive equipment, limited scalability, or stability concerns. Among these approaches, the solid dispersion technique has emerged as one of the most effective, economical, and industrially feasible methods for enhancing the dissolution rate of poorly water-soluble drugs^(3,6)

Solid dispersion is defined as the dispersion of one or more active pharmaceutical ingredients in an inert hydrophilic carrier in the solid state. The concept was first introduced by Chiou and



Riegelman in 1971 and has since become one of the most extensively investigated solubility enhancement techniques. Hydrophilic carriers such as polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), poloxamers, hydroxypropyl methylcellulose (HPMC), Soluplus®, and Eudragit® are widely employed because they improve drug wettability, reduce particle size, increase surface area, inhibit drug crystallization, and often convert crystalline drug into an amorphous form, thereby markedly enhancing dissolution and oral bioavailability⁽⁶⁾

The enhancement in drug dissolution from solid dispersions occurs through several physicochemical mechanisms. These include molecular dispersion of drug particles, reduction in particle size, increased wettability, improved porosity, decreased aggregation, higher surface free energy, formation of amorphous systems, and inhibition of recrystallization during dissolution. Hydrophilic polymers dissolve rapidly in gastrointestinal fluids, exposing a large effective surface area of the dispersed drug and maintaining supersaturated drug concentrations for prolonged periods, which significantly improves dissolution kinetics and drug absorption^(2,3)

Numerous researchers have successfully developed gliclazide solid dispersions using carriers such as PEG 4000, PEG 6000, PVP K30, PVP K90, Poloxamer 188, Poloxamer 407, cross-linked polyvinylpyrrolidone, amorphous silica, and combinations of hydrophilic polymers. These formulations have demonstrated several-fold improvements in saturation solubility and dissolution rate compared with pure gliclazide. Physicochemical characterization using differential scanning calorimetry (DSC), powder X-ray diffraction (PXRD), Fourier-transform infrared spectroscopy (FTIR), and scanning electron microscopy (SEM) has confirmed decreased crystallinity, enhanced wettability, and

partial or complete amorphization of gliclazide in optimized formulations⁽⁷⁾

Various preparation methods have been employed for developing gliclazide solid dispersions, including fusion (melting), solvent evaporation, spray drying, hot-melt extrusion, freeze drying, co-grinding, kneading, microwave-assisted processing, and supercritical fluid technology. Selection of an appropriate preparation technique depends on drug stability, carrier properties, manufacturing feasibility, scalability, regulatory requirements, and the desired release characteristics. Modern continuous manufacturing technologies such as hot-melt extrusion and spray drying have further improved the commercial applicability of solid dispersion systems. Characterization of gliclazide solid dispersions involves evaluation of drug content, saturation solubility, dissolution profile, particle size, thermal behavior, crystallinity, drug-polymer compatibility, morphology, stability, and in some cases in vivo pharmacokinetic performance. Advanced analytical techniques including DSC, PXRD, FTIR, Raman spectroscopy, SEM, transmission electron microscopy (TEM), and nuclear magnetic resonance (NMR) provide valuable information regarding molecular interactions and structural changes responsible for enhanced dissolution behavior^(2,6)

The present review aims to provide a comprehensive overview of the formulation design, mechanisms of solubility enhancement, hydrophilic carriers, preparation methods, characterization techniques, recent research findings, advantages, limitations, future prospects, and industrial significance of gliclazide solid dispersions. The review highlights the potential of solid dispersion technology as an effective strategy for improving the solubility, dissolution rate, oral bioavailability, and therapeutic performance of gliclazide, thereby supporting the development of more efficient oral antidiabetic formulations.



DRUG PROFILE OF GLICLAZIDE

Gliclazide is a second-generation sulfonylurea oral antidiabetic drug used in the treatment of **Type 2 diabetes mellitus**. It lowers blood glucose levels by stimulating insulin secretion from pancreatic β -cells through inhibition of ATP-sensitive potassium (KATP) channels. In addition to its hypoglycemic action, gliclazide exhibits antioxidant and vascular protective effects, making it effective in reducing the risk of diabetic microvascular complications.^(8,9)

Gliclazide belongs to the **Biopharmaceutics Classification System (BCS) Class II**, characterized by **low aqueous solubility and high permeability**. Its poor water solubility limits its dissolution rate and oral bioavailability, making it an ideal candidate for solubility enhancement techniques such as **solid dispersion technology**. Hydrophilic carriers used in solid dispersions improve the drug's wettability, reduce crystallinity, increase dissolution rate, and enhance oral absorption.⁽¹⁰⁾

Drug Profile

Parameter	Details
Generic Name	Gliclazide
Drug Class	Second-generation sulfonylurea
Therapeutic Class	Oral antidiabetic agent
Indication	Type 2 Diabetes Mellitus
Molecular Formula	$C_{15}H_{21}N_3O_3S$
Molecular Weight	323.41 g/mol
BCS Class	II (Low solubility, High permeability)
Mechanism of Action	Stimulates insulin secretion by blocking KATP channels in pancreatic β -cells
Route of Administration	Oral
Dosage Forms	Immediate-release and modified-release tablets
Half-life	Approximately 10–12 hours
Metabolism	Hepatic (mainly CYP2C9)
Excretion	Primarily via urine as metabolites

SOLID DISPERSION TECHNOLOGY

Solid dispersion (SD) technology is one of the most effective pharmaceutical approaches for enhancing the solubility, dissolution rate, and oral bioavailability of poorly water-soluble drugs. The concept was first introduced by Chiou and Riegelman in 1971, who defined solid dispersions as the dispersion of one or more active pharmaceutical ingredients in an inert carrier or matrix in the solid state. Since then, solid dispersion technology has become an important formulation strategy for Biopharmaceutics Classification System (BCS) Class II and Class IV

drugs, where poor aqueous solubility limits oral absorption⁽¹¹⁾

The principle of solid dispersion involves dispersing a poorly soluble drug at the molecular, colloidal, or particulate level within a hydrophilic polymeric carrier. The hydrophilic carrier dissolves rapidly in gastrointestinal fluids, increasing drug wettability, reducing particle size, enhancing surface area, decreasing crystallinity, and often converting the drug into an amorphous state. These physicochemical changes markedly improve drug dissolution and subsequently increase oral bioavailability⁽¹²⁾

Solid dispersion systems are widely employed because they are relatively simple to formulate,



economical, scalable, and compatible with conventional pharmaceutical manufacturing processes. Hydrophilic carriers such as polyethylene glycol (PEG), polyvinylpyrrolidone (PVP), hydroxypropyl methylcellulose (HPMC), poloxamers, Soluplus®, copovidone, and Eudragit® are commonly used due to their excellent solubilizing ability and capacity to stabilize amorphous drug forms⁽¹³⁾

For poorly soluble drugs such as gliclazide, dissolution is the rate-limiting step in gastrointestinal absorption. Solid dispersion technology significantly enhances drug dissolution by improving wettability, reducing particle aggregation, increasing porosity, promoting molecular dispersion, and preventing recrystallization. Consequently, this technique has been extensively investigated for improving the therapeutic performance of gliclazide and many other BCS Class II drugs.

Solid dispersions are generally classified into first-, second-, third-, and fourth-generation systems based on the nature of the carrier employed. First-generation solid dispersions utilize crystalline carriers, second-generation systems employ amorphous polymeric carriers, third-generation systems incorporate surfactants or self-emulsifying carriers to improve dissolution and stability, while fourth-generation solid dispersions are designed for controlled or sustained drug release.

The mechanisms responsible for enhanced drug dissolution from solid dispersions include molecular dispersion of the drug, particle size reduction to the molecular level, improved wettability, increased porosity, amorphization, inhibition of crystal growth, enhanced surface free energy, and stabilization of supersaturated drug solutions. These mechanisms collectively contribute to rapid dissolution, improved gastrointestinal absorption, enhanced oral

bioavailability, reduced dose variability, and superior therapeutic efficacy.

METHODS OF PREPARATION OF SOLID DISPERSION

Several techniques have been developed for the preparation of solid dispersions. The selection of an appropriate method depends on the physicochemical properties of the drug and carrier, thermal stability, solvent compatibility, desired drug release profile, and industrial scalability.

1. Fusion (Melting) Method The fusion or melting method is the simplest and oldest technique for preparing solid dispersions. In this method, the hydrophilic carrier is heated above its melting point until a homogeneous molten mass is obtained. The drug is then incorporated into the molten carrier with continuous stirring to ensure uniform dispersion. The resulting melt is rapidly cooled to room temperature or on an ice bath to prevent drug recrystallization. The solidified mass is crushed, pulverized, and sieved to obtain particles of the desired size. This method is suitable for thermally stable drugs and carriers such as polyethylene glycol (PEG), poloxamers, and Gelucire®. It is solvent-free, economical, and easy to scale up; however, it is not suitable for thermolabile drugs due to the possibility of thermal degradation.⁽¹⁴⁾

2. Solvent Evaporation Method

In the solvent evaporation method, both the drug and hydrophilic carrier are dissolved in a common volatile solvent such as ethanol, methanol, acetone, or chloroform to obtain a clear solution. The solvent is removed by evaporation under reduced pressure using a rotary evaporator or by drying at controlled temperature. The dried solid mass is pulverized and sieved to obtain the final solid dispersion.



This method is particularly useful for thermosensitive drugs because it avoids exposure to high temperatures. However, complete removal of residual organic solvents is essential to ensure product safety and regulatory compliance.⁽¹⁴⁾

3. Hot-Melt Extrusion (HME)

Hot-melt extrusion is an advanced continuous manufacturing technique widely employed in the pharmaceutical industry. The drug and polymer are blended and fed into a heated extruder, where rotating screws mix and melt the components under controlled temperature and shear. The homogeneous molten mixture is forced through a die, cooled, and milled into the desired particle size.

Hot-melt extrusion provides excellent content uniformity, reproducibility, and scalability while eliminating the need for organic solvents. It is particularly suitable for preparing amorphous solid dispersions.⁽¹⁵⁾

4. Spray Drying Method

Spray drying involves dissolving the drug and polymer in a suitable solvent followed by atomization of the solution into a stream of heated air. Rapid solvent evaporation results in the formation of fine dry particles containing molecularly dispersed drug.

This technique produces particles with high surface area, excellent flowability, rapid dissolution, and improved bioavailability. Spray drying is widely used for commercial production of amorphous solid dispersions.⁽¹⁶⁾

5. Freeze Drying (Lyophilization)

Freeze drying involves dissolving or dispersing the drug and carrier in an appropriate solvent followed by freezing at very low temperatures. Ice crystals are removed by sublimation under vacuum, producing a highly porous solid matrix.

Lyophilization minimizes thermal degradation and preserves the amorphous

nature of the drug. However, the process is expensive, time-consuming, and generally limited to heat-sensitive compounds.⁽¹⁷⁾

6. Kneading Method

In the kneading method, the polymer is mixed with a small quantity of solvent to produce a paste-like mass. The drug is gradually incorporated with continuous kneading until a homogeneous mixture is obtained. The resulting mass is dried, pulverized, and sieved.

This method is simple, inexpensive, and requires minimal equipment, making it suitable for laboratory-scale preparation.⁽¹⁶⁾

7. Co-Grinding Method

Co-grinding or mechanochemical activation involves simultaneous grinding of the drug and carrier using a mortar and pestle or ball mill. Mechanical energy reduces particle size, improves intimate contact between drug and polymer, and may partially convert the crystalline drug into an amorphous state.

The technique is solvent-free, environmentally friendly, and economical.⁽¹⁷⁾

8. Supercritical Fluid Technology

Supercritical fluid technology utilizes supercritical carbon dioxide as a processing medium. Drug and polymer are dissolved or suspended in the supercritical fluid, followed by rapid expansion or solvent extraction to obtain fine particles with enhanced dissolution characteristics.

This technique produces solvent-free products with narrow particle-size distribution but requires sophisticated and expensive equipment.

9. Microwave-Assisted Method

Microwave irradiation generates rapid internal heating, allowing homogeneous melting of the drug and polymer. The molten mixture is cooled, pulverized, and sieved to produce the solid dispersion.



The method reduces processing time, improves energy efficiency, and minimizes thermal degradation compared with conventional heating.⁽¹⁸⁾

10. Electrospinning

Electrospinning is an emerging technique in which a polymeric drug solution is subjected to a high-voltage electric field to produce ultrafine nanofibers. The rapid evaporation of solvent during fiber formation yields amorphous solid dispersions with extremely high surface area and excellent dissolution characteristics.

Electrospinning is particularly useful for developing advanced drug delivery systems and personalized dosage forms.

CHARACTERIZATION TECHNIQUES OF SOLID DISPERSIONS

Characterization of solid dispersions is essential to evaluate the physicochemical properties, drug–polymer interactions, crystallinity, morphology, stability, and dissolution behavior of the formulation. Comprehensive characterization ensures the quality, performance, and reproducibility of solid dispersion systems.^(19,20,21)

1. Drug Content Determination

Drug content analysis is performed to determine the uniform distribution of the drug within the carrier matrix. An accurately weighed quantity of solid dispersion equivalent to the required amount of drug is dissolved in a suitable solvent and analyzed using UV-Visible spectrophotometry or High-Performance Liquid Chromatography (HPLC). Drug content is generally expressed as the percentage of labeled drug present in the formulation.

2. Saturation Solubility Study

Saturation solubility studies evaluate the improvement in drug solubility after formulation. Excess solid dispersion is added

to distilled water or suitable dissolution media and shaken continuously for 24–48 hours at $37 \pm 0.5^\circ\text{C}$ until equilibrium is reached. The solution is filtered and analyzed spectrophotometrically or by HPLC. Increased saturation solubility indicates successful enhancement of drug dissolution.

3. In-vitro Dissolution Study

Dissolution testing is the most important evaluation parameter for solid dispersions. The study is performed using the USP Dissolution Apparatus I (Basket) or Apparatus II (Paddle) in suitable dissolution media maintained at $37 \pm 0.5^\circ\text{C}$. Samples are withdrawn at predetermined intervals, filtered, and analyzed spectrophotometrically. Dissolution profiles of the solid dispersion are compared with those of the pure drug to assess improvement in dissolution rate.

4. Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectroscopy is employed to investigate drug–polymer compatibility and identify possible chemical interactions. The spectra of the pure drug, polymer, physical mixture, and solid dispersion are recorded over the range of $4000\text{--}400\text{ cm}^{-1}$. The absence of significant shifts or disappearance of characteristic peaks indicates chemical compatibility, whereas changes in peak position or intensity may suggest hydrogen bonding or molecular interactions.

5. Differential Scanning Calorimetry (DSC)

Differential Scanning Calorimetry is used to evaluate the thermal behavior of solid dispersions. DSC measures heat flow associated with melting, crystallization, and glass transition. The disappearance or reduction of the drug's melting endotherm indicates conversion from the crystalline to the amorphous state, confirming successful formation of a solid dispersion.



6. Powder X-ray Diffraction (PXRD)

PXRD is used to determine the crystalline or amorphous nature of the drug within the solid dispersion. Pure crystalline drugs exhibit sharp and intense diffraction peaks, whereas amorphous systems produce broad halos with reduced peak intensity. Decreased crystallinity generally correlates with improved solubility and dissolution.

7. Scanning Electron Microscopy (SEM)

SEM is employed to examine the surface morphology, particle size, and surface characteristics of solid dispersions. SEM images reveal changes in particle shape, surface roughness, porosity, and aggregation. The disappearance of characteristic drug crystals indicates successful molecular dispersion within the carrier.

8. Transmission Electron Microscopy (TEM)

TEM provides high-resolution images of the internal structure of solid dispersions. It is useful for evaluating particle size, particle distribution, and nanoscale morphology. TEM can confirm homogeneous dispersion of drug particles within the polymeric matrix.

9. Stability Studies

Stability studies are conducted according to ICH guidelines under accelerated ($40 \pm 2^\circ\text{C}/75 \pm 5\% \text{ RH}$) and long-term storage conditions. Samples are periodically evaluated for appearance, drug content, dissolution profile, crystallinity, and thermal behavior. Stability studies determine whether the amorphous drug recrystallizes during storage and ensure long-term product quality.

ADVANTAGES AND LIMITATIONS OF SOLID DISPERSION TECHNOLOGY

➤ Advantages

1. **Improved Aqueous Solubility** Solid dispersions significantly increase the apparent

solubility of poorly soluble drugs by dispersing the drug within hydrophilic carriers. This facilitates rapid interaction between the drug and dissolution medium, resulting in enhanced drug solubility

2. **Enhanced Dissolution Rate** The drug is present in a molecularly dispersed or amorphous state with reduced particle size and increased surface area, leading to a much faster dissolution rate than the pure crystalline drug
3. **Increased Oral Bioavailability** Improved dissolution enhances gastrointestinal absorption, resulting in increased oral bioavailability, reduced interpatient variability, and improved therapeutic efficacy
4. **Reduction in Drug Crystallinity** Conversion of crystalline drug into an amorphous form increases molecular mobility and free energy, thereby improving dissolution and drug release
5. **Improved Wettability** Hydrophilic polymers improve the wettability of drug particles, allowing dissolution media to penetrate rapidly and dissolve the drug more efficiently
6. **Uniform Drug Distribution** Drug molecules are uniformly distributed throughout the polymer matrix, minimizing aggregation and ensuring consistent drug release.^(22,23)

➤ Limitations

1. **Physical Instability** The amorphous drug may recrystallize during storage because of temperature, humidity, or molecular mobility, resulting in reduced solubility and dissolution.
2. **Moisture Sensitivity** Many hydrophilic polymers are hygroscopic and absorb atmospheric moisture, affecting stability and performance.
3. **Thermal Degradation** Fusion-based methods require elevated temperatures, making them unsuitable for thermolabile drugs.



4. **Residual Organic Solvents** Solvent evaporation techniques may leave traces of residual solvents that require careful removal to comply with regulatory guidelines.
5. **Polymer Compatibility Issues** Not every polymer is compatible with every drug. Poor compatibility may lead to phase separation or instability.
6. **Scale-Up Challenges** Some laboratory preparation techniques are difficult to reproduce on an industrial scale.⁽²⁴⁾

FUTURE PERSPECTIVES

1. Development of novel hydrophilic polymers and polymeric blends to improve the stability of gliclazide solid dispersions.
2. Utilization of advanced manufacturing techniques such as hot-melt extrusion and spray drying for large-scale production.
3. Application of Quality by Design (QbD) and Process Analytical Technology (PAT) to optimize formulation development and manufacturing.
4. Exploration of nanotechnology-based solid dispersions to further enhance solubility, dissolution, and oral bioavailability.
5. Development of supersaturating solid dispersion systems to maintain prolonged drug supersaturation and improve absorption.
6. Investigation of three-dimensional (3D) printing technology for personalized gliclazide dosage forms.
7. Evaluation of novel carriers such as Soluplus®, copovidone, amphiphilic polymers, and polymeric surfactants for improved formulation performance.

CONCLUSION

Gliclazide is a BCS Class II antidiabetic drug with poor aqueous solubility, which limits its dissolution and oral bioavailability. Solid

dispersion technology is an effective approach to overcome these limitations by improving drug wettability, reducing crystallinity, and enhancing dissolution rate. Various preparation methods and hydrophilic carriers have demonstrated significant improvements in the physicochemical and biopharmaceutical properties of gliclazide. Overall, solid dispersion technology represents a simple, reliable, and promising formulation strategy for enhancing the therapeutic efficacy and oral bioavailability of gliclazide.

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