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SOLUPLUS - SOLID DISPERSION FOR ENHANCED DRUG DELIVERY

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Abstract

Many drugs have poor water solubility, which reduces their effectiveness. Solid dispersions are used to enhance the dissolution of such drugs. Soluplus, a polymer, improves drug solubility, prevents crystallization, and enhances absorption. It can be incorporated using techniques such as hot-melt extrusion, spray drying, and solvent evaporation. Incorporating Soluplus in solid dispersions improves drug performance and facilitates better bioavailability.

Introduction

Solid dispersion is one of the most effective approaches to improve the solubility and dissolution rate and hence the bioavailability of poorly water-soluble drugs. However, a major limitation of solid dispersion is that amorphous drug is thermodynamically unstable and tends to re-crystallize during storage, especially when trace amount of crystalline drug is left in solid dispersion which will act as nudeating agents to accelerate re-crystallization of amorphous drug substance. Therefore, complete transformation of crystal line drug to amorphous state is the key point to improve physical stability and dissolution performance of the solid dispersion. Nowadays, the term solid dispersion is mostly linked to glass solutions of poorly soluble compounds, using amorphous carriers with high glass transition temperatures. The primary aim of fast release glass solutions is to molecularly release the drug in the intestinal fluids and to generate a supersaturated solution from which the drug will move to the gut wall, permeate and finally appear in the blood.

Soluplus a polyethylene glycol–polyvinyl acetate–polyvinyl caprolactam-based graft copolymer (PVAc–PVCap–PEG), has been studied extensively in ASDs of several investigational, and model drugs in hot melt extrusion, spray drying, high shear dispersions, Kinetisol electro spinning/electro spraying, microwave radiation, solvent casting, solvent evaporation, ball milling, physical/co-milling blends, and thermal heating amongst others.

Soluplus shows excellent solubilizing properties for BCS class II and IV drugs and offers the possibility of producing solid solutions of several drugs of poor water solubility using extrusion techniques. Compared the electro spun and extrusion techniques in the development of Soluplus solid solutions of the poorly water-soluble drug, spironolactone. Unfortunately, extrusion technique suffers some disadvantages comprising the high processing temperature and the shear stress, which might influence the polymer and drug stability during production and storage. Another important disadvantage is the limited number of available polymers; thus requires pharmaceutical grade polymers that can be processed at relatively low temperatures limiting the variety of possible formulations.

Among Amphilphilic block coploymers, soluplus (SLP, here after), an Amphilphilic water-soluble graft copolymer

developed by BASF, stands out as particularly effective in addressing the solubility challenges posed by poorly water-soluble drugs as well as a matrix polymer for solid solutions until now, most articles dealing with SLP have focused on the features and applications of this copolymer in drug delivery, highlighting its advantages, drug incorporation methods, and the physicochemical characteristics of SLP-based formulations. In this review, we have focused on the biomedical applications of this polymer. This review is structured to explore the physicochemical properties of SLP, followed by a discussion of potential formulation methods, and concludes with some of its relevant biomedical applications.

Soluplus polymer is a versatile excipient that primarily benefits drug formulations by enhancing the solubility and bioavailability of poorly water-soluble drugs, preventing their recrystallization in solid dispersions, and stabilizing various dosage forms like Nano micelles and nanosuspensions.

1. Hydrophilicity Vs Amphilphilicity

Other polymers (eg:-HPMC, PVP) mostly hydrophilic, dissolve we in water but have limited ability to solubilize very lipophilic drugs. Soluplus; Amphilphilic this allow it to interact with both water and fat-soluble drugs, improving solubility much more effectively.

2. Molecular weight

Typical polymers like PVP K30-molecuweight~40,000g/mol, HPMC even higher. Soluplus -Moderate MW ~90,000-14,000g/mol giving a balance of stability and process ability without too much viscosity.

3. Glass Transition temperature

HPMC, PVP, HPMCAS- often higher Tg(>100°C),making them harder to process by hot melt- extrusion unless particle size are added. Soluplus -Tg~70°c, easier to extrude and process, even with thermoliable drugs.

4. Solubility behaviour

Other polymers -hydrophilic, only dissolve but don't form micelles. Soluplus – Amphilphilic, can form micelles in solution and encapsulated lipophilic drugs, leading to higher solubility.

5. Drug- polymer interaction

HPMC/PVP – mainly hydrogen bonding, some time weaker. Soluplus – provides hydrogen bonding + hydrophobic interactions, giving stronger stabilization of amorphous drug and better inhibition of recrystallization.

6. Viscosity in solution

HPMC -High viscosity, may slow drug release and complicate processing. Soluplus -lower viscosity solutions, easier handling, and better suitability for spray drying or nanosuspensions.

7. Stability of Solid Dispersions

Other polymers – May allow recrystallization over time. Soluplus – provides better long- term stability due to strong drug – polymer and Amphilphilic stabilization.

Physical properties

Soluplus is an amorphous, white to off-white graft copolymer that exhibits unique physical characteristics highly suitable for solid dispersion technology. Its amorphous nature plays a critical role in maintaining drugs in a non-crystalline, high-energy state, thereby improving dissolution and bioavailability. The polymer has a glass transition temperature of about 70 °C, which ensures the stability of solid dispersions during processing and storage. Soluplus demonstrates excellent aqueous solubility as well as good solubility in organic solvents, making it versatile for different formulation techniques such as hot melt extrusion and spray drying. Due to its amphiphilic character, containing both hydrophilic polyethylene glycol and lipophilic vinyl acetate and caprolactam segments, Soluplus enhances drug wettability and promotes micelle formation upon contact with gastrointestinal fluids. The polymer also shows lowviscosity in solution, enabling high drug loading without processing difficulties. Additional physical attributes such as good flowability, compressibility, moderate hygroscopicity, and film-forming ability further strengthen its application in oral dosage forms.

with a distinctive advantage in stabilizing poorly soluble drugs and ensuring their effective delivery through solid dispersion systems.

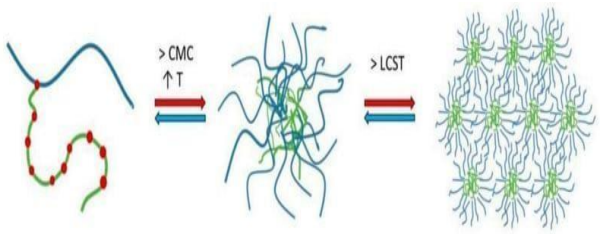

Fig 01: Micellisation mechanism and behaviour of soluplus.

Chemical Properties

Soluplus is an amphiphilic graft copolymer composed of polyvinyl caprolactam, polyvinyl acetate, and polyethylene glycol segments. Its unique chemical architecture imparts both hydrophilic and lipophilic characteristics, enabling it to function as an effective carrier in solid dispersion systems for poorly water-soluble drugs.

The amphiphilic nature of Soluplus allows interaction with hydrophobic drug molecules through the vinyl caprolactam and vinyl acetate moieties, while the polyethylene glycol chains ensure water solubility and compatibility with biological systems. The polymer contains functional groups such as amide (–CONH–) and ester (–COO–) linkages, which are capable of forming hydrogen bonds with drug molecules. These interactions play a crucial role in stabilizing the amorphous state of drugs within solid dispersions and inhibiting recrystallization during storag.

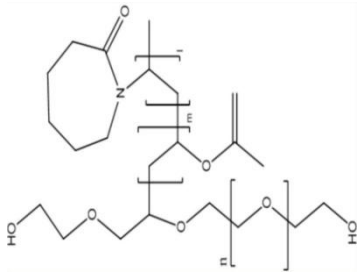

Fig 02: Chemical structure of Soluplus

Being a nonionic polymer, Soluplus is chemically stable across the physiological pH range (1.2– 7.4) and does not undergo ionic interactions that could compromise drug release. It also demonstrates excellent thermal stability (stable up to ~200 °C), making it suitable for processing techniques such as hot-melt extrusion and spray drying. Its glass transition temperature (Tg ≈ 70 °C) is sufficiently high to maintain drug–polymer systems in a kinetically stabilized amorphous form.

In aqueous media, Soluplus exhibits self-micellization behavior (critical micelle concentration ≈ 0.0003 M), where the hydrophobic segments form a micellar core encapsulating poorly soluble drugs, while the hydrophilic PEG chains stabilize the micelles in solution. This property significantly improves drug wettability, dissolution rate, and ultimately, oral bioavailability.

Collectively, these chemical properties amphiphilicity, hydrogen bonding potential, nonionic character, thermal and pH stability, micellization ability, and favorable Tg- make Soluplus® an efficient polymer for developing solid dispersions aimed at enhancing solubility, dissolution, and bioavailability of BCS class II and IV drugs.

Soluplus Design Models for Various Formulations

Tablets

As a binder and matrix forming agent, Soluplus plays a crucial role in preparation of oral solid dosage forms such as tablets and capsules. Its ability to form robust matrices helps in controlling drug release kinetics and ensuring formulation integrity. Moreover, Soluplus® contributes to the mechanical strength and disintegration properties of tablets, enabling precise dose administration and enhanced patient compliance. Soluplus plays a pivotal role as a direct compression aid in pharmaceutical tablet formulations, owing to its unique characteristics and versatile functionality.

As a polymeric excipient, Soluplus facilitates the direct compression process by serving as a binder, disintegrant, and lubricant simultaneously. Its ability to form a cohesive matrix around drug particles promotes tablet integrity and uniformity, ensuring the consistent release of the active pharmaceutical ingredient (API). Furthermore, Soluplus aids in the rapid disintegration of tablets upon ingestion, enhancing drug dissolution and bioavailability. Its lubricating properties contribute to smoother tablet compression, reducing friction between the tablet blend and the compression tooling surfaces. Moreover, Soluplus offers formulation flexibility, as it is compatible with a wide range of APIs and excipients commonly used in direct compression formulations. Overall, Soluplus emerges as a valuable component in direct compression tablet manufacturing, streamlining the process while ensuring the quality, efficacy and patient compliance of the final dosage form. Hot melt extrusion - soluplus serves as a highly effective component in hot melt extrusion (HME) processes, offering numerous advantages in pharmaceutical formulation. As a thermoplastic polymer, Soluplus can be melted and processed at relatively low temperatures, making it well-suited for HME applications. During the extrusion process, Soluplus acts as both a binder and a carrier for active pharmaceutical ingredients (APIs), facilitating uniform distribution and controlled release. Its amphiphilic nature enables Soluplus to interact with both hydrophilic and hydrophobic components, ensuring compatibility with a wide range of drug substances. Furthermore, Soluplus enhances the stability of APIs, protecting them from degradation and oxidation during processing. By forming stable dispersions and solid solutions, Soluplus enables the formulation of various dosage forms, including tablets, films, and implants, with improved bioavailability and therapeutic efficacy. Overall, Soluplus emerges as a versatile and efficient material in HME processes, offering enhanced formulation flexibility, stability, and performance in pharmaceutical manufacturing, the aim of their study was to utilize the viscoelastic characteristics of polymer and drug polymer blends in order to identify optimal processing parameters for creating amorphous solid dispersions through melt extrusion. In their research, the focus was on a poorly water-soluble medication, carbamazepine (CBZ), which was combined with Soluplus® as the carrier material. Itraconazole soluplus solid dispersions with 50% (w/w) drug loading prepared by hot melt extrusion (HME) were investigated.

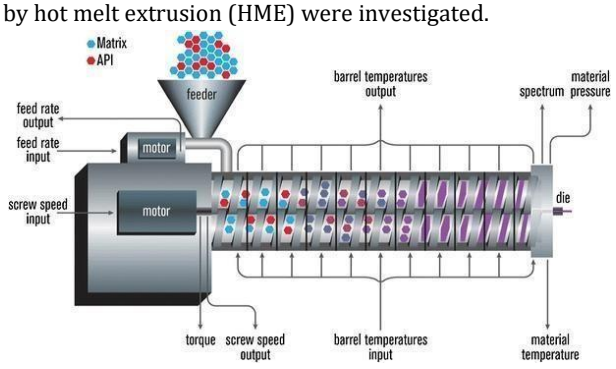

Fig 03: Hot melt extrusion for tablets

Capsules Formulation

capsule formulation is a wide used method in the pharmacutical industry, particularly for poorly so luble compounds.Due to its self-aggregation properties,soluplus can solubilized hydrophobic drugs,which can significantly improve their dissolution rates and boiavilability when administered orally as mentioned above soluplus is

compatible with variety of solvents and therefore can be incorporated into different capsules dispersion or as a components of self-emulsifying drug delivery system (SEDDS).

The ability of soluplus to form stable, amorphous solid dispersions helps prevent recrystallization which is common issue with poorly soluble drugs. Furthermore the use of soluplus in capsules is advantageous because it ensures a more consistent and rapid absorption of the active compound in the gastrointestinal tract. Some recent studies have described the use of soluplus for instsnce, investigated formulations of gliclazide, a challenging compound in terms of solubility. They prepare solid dispersions of the drug with soluplus in a 1:8 ratio using solvent evaporation. Then, the produce was formulated into gelatin capsules, which showed improved dissolution profiles compared with the physical mixture drug polymer.

Spray Drying

It is a widely employed technique for the preparation of solid dispersions of poorly soluble drugs using soluplus as a polymer, particularly for oral capsule formulations. In this process, the drug and soluplus are first dissolved in a suitable volatile solvent or solvent mixture to form a homogeneous feed solution. This solution is then atomized into fine droplets using a nozzle or rotary atomizer and introduced into a hot drying chamber, where rapid solvent evaporation occurs. As the solvent evaporates, the drug becomes dispersed within the soluplus matrix, forming a solid , amorphous powder .The powder is collected and filled into capsules. The resulting capsules exhibit enhanced drug solubility, improved dissolution rates and bioavailability due to amorphous nature of the drug within the soluplus carrier.

Oral Formulations

Nanoparticles and Micro Particles

Soluplus is also widely applied in the design of nano and microparticle delivery systems. Acting as both a stabilizer and a dispersing agent, it helps to maintain uniform particle distribution and prevents aggregation. This leads to better colloidal stability and enables sustained or controlled drug release. By adjusting particle size and surface features, Soluplus® - Basic nanoparticles can be engineered for targeted delivery and improve therapeutic efficiency. Studies have also exploded combining sold luck with transit Philip copolymer such as DSPE – PEG2000 to prepare stable nano systems using hydration- based methods.

Surfactant

Soluplus has surfactant - like properties that make it valuable in pharmaceutical formulations, especially weight poorly soluble drugs need to be dispersed or emulsified. As a surfactant, it reduces that surface tension between immiscible phases such as oil and water, allowing stable emulsions or dispersions to form. This improves solubility, dissolution and ultimately bioavailability of hydrophobic drugs. In addition soluplus helps to prevent droplet aggregation, ensuring long term stability of emulsified systems. It plays a dual role as both a polymeric carrier and surfactant has been shown enhance oral absorption, for example lopinavir.

Topical Formulations

Topical drug delivery is an important route for local and systemic therapy, but many drugs suffer from poor water solubility, limiting their bioavailability. Soluplus, an amphilic graft copolymer composed of polyvinyl caprolactam, polyvinyl acetate, and polyethylene glycol, has emerged as a versatile polymer for enhancing solubility and stability of poorly water – soluble drugs. Its unique properties, including solubilization, film formation make it highly suitable for ointments formulation. The SEM method is commonly used.

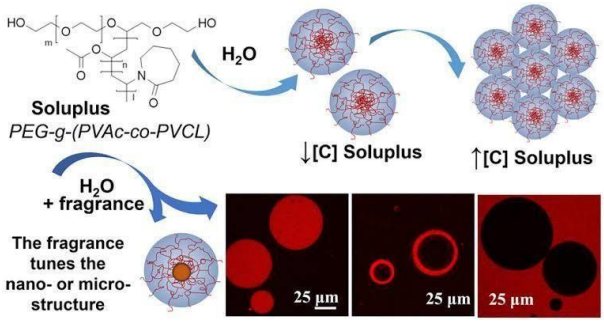

Fig 04: Self-assembly of Soluplus in aqueous solution.

Solvent Evaporation Method

The solvent Evaporation method is widely used for preparing solid dispersions in ointment formulations. It is effective for improving the solubility of poorly - water soluble drugs. Soluplus, an amphiphilic polymer, act as carriers in this process. The drug and soluplus are dissolved together in a suitable volatile solvent to form a homogeneous solution. This ensures uniform drug distribution within the polymer matrix. The solution is subjected to controlled solvent evaporation, often under reduced pressure. As the solvent evaporates, the drug becomes molecularly dispersed in the soluplus polymer. This dispersion enhances drug solubility, stability and bioavailability in the ointments. The resulting solid dispersion is then incorporated into a semi-solid ointment base. Common bases include petroleum jelly, paraffin, or hydrophilic ointment bases. Incorporation maintains the enhanced solubility while ensuring proper spreadability and consistency. The ointment provides uniform drug distribution and sustained topical release. Overall, solvent Evaporation using soluplus is a robust strategy for developing ointments with enhanced solubility, drug delivery and therapeutic efficiency.

Table 01: Various Formulations

Dosage Form	Design Model	Principle	Advantages
Tablets	Hot melt extrusion	Drugs and soluplus melted and extruded into solid dispersion.	Improves solubility, uniform distribution and suitable for controlled release.
Capsules	Spray drying	Drug-polymer solution Converted into fine powder.	Rapid dissolution, suitable for Poorly soluble drugs.
Oral formulations	Nanoparticles and microparticles	Drug loaded particles for oral use.	Controlled release, targeted delivery.
Topical	Solvent evaporation method	Drug – soluplus dispersion incorporated into ointments.	Enhances skin penetration, controlled Release, stable formulation.

Applications

- In the previous section we have described a survey of the recent literature on the use of SLP in pharmaceutical formulations. SLP has demonstrated versatility in delivering diverse drug types, including antitumoral, anti-inflammatory, antimicrobial, and antiparasiti agents.
- Its biocompatibility and stability prompt its use as a carrier in various drug delivery systems, such as nanoparticles, micelles, and solid dispersions, enabling targeted delivery, sustained release, and reduced side effects.
- By optimizing drug solubility and enhancing bioavailability, formulations with SLP offer solutions to current challenges in treating complex diseases.

Applications	Suitable for capsule and tablet formulations
Solubility enhancement	Enhances solubility of poorly soluble drugs
Processing techniques	Amorphous solid solutions, hot melt extrusion, Spray drying, and drug polymer layering.
Bioavailability enhancement	Demonstrated significant increase in Bioavailability for poorly water soluble APIs
Glass transition temperature (Tg)	~70°C
Flow coefficient (Kv value ; 1 %ethanol)	31-41
Minimum ignition energy	10-30mj
Lower crystalline solution temperature (LCST)	~40°C
HLB Approximately-14	~14

Soluplus finds application in the formulation of nano and microparticles for various drug delivery systems. Acting as a stabilizer and surfactant, it facilitates the dispersion and stabilization of drug particles, leading to improved colloidal stability and sustained release profiles.

Advantages

- **Enhanced Solubility**: Soluplus effectively boosts the solubility of poorly water-soluble drugs by forming micelles in water, which encapsulate hydrophobic drug molecules, thus improving their solubility and absorption.
- **Improved Stability**: Soluplus enhances the stability of drugs, safeguarding them from degradation or aggregation by shielding them from environmental factors like light, heat, and oxidation.
- **Streamlined Formulation Development**: Soluplus versatility and compatibility with various processing methods make it a valuable asset in developing different dosage forms such as tablets, capsules, and oral films.
- **Advanced Drug Delivery**: Acting as a carrier in drug delivery systems like nanoparticles and microparticles, Soluplus capacity to form stable dispersions makes it ideal for administering drugs through various routes.
- **Taste-Masking**: Soluplus effectively masks the bitter taste of drugs in oral formulations, which is particularly beneficial for enhancing patient acceptance, notably in pediatric and geriatric populations.
- **Convenient Handling**: Thanks to its favorable flow properties and compatibility with common pharmaceutical excipients, Soluplus is easy to handle during formulation processes.
- **Regulatory Acceptance**: Having been incorporated into numerous pharmaceutical products and receiving regulatory approval in multiple countries, Soluplus established record eases its adoption in drug development and commercialization.

Conclusion

Soluplus is a multifunctional polymer widely utilized to enhance the solubility and bioavailability of poorly water-soluble drugs through solid dispersion technology. Its key characteristics-including excellent drug miscibility,

physicochemical stability, and crystallization inhibition-make it an effective carrier system. Soluplus-based solid dispersions can be prepared using various formulation techniques such as hot-melt extrusion, spray drying, and solvent evaporation. By improving drug dissolution, absorption, and overall therapeutic performance, Soluplus serves as a valuable excipient in modern drug delivery systems.

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Conflict of Interest

Not Declared

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Inform Consent and ethical statement

Not Applicable

Authors Contribution

All authors are contributed equally

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