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ROLE OF GELUCIRE IN SOLUBILITY ENHANCEMENT: A COMPREHENSIVE REVIEW

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ABSTRACT: The aim of this article is to provide a comprehensive review of Gelucire as an effective excipient for improving the solubility and bioavailability of poorly water-soluble drugs. Gelucire, a family of lipid-based, amphiphilic excipients, has emerged as a valuable carrier for enhancing the solubility and dissolution of poorly soluble drugs. Gelucire combines hydrophilic polyethylene glycol esters and lipophilic glycerides, enabling self-emulsification, improved wettability, and formation of stable solid dispersions. Different types of Gelucire are used in oral and topical formulations to improve drug release profiles, bioavailability, and stability. This review discusses Gelucire's chemical nature, hydration behaviour, and applications in solid dispersions for solubility enhancement. There are other various solubility improvement methods like chemical, physical, and advanced techniques with an emphasis on solid dispersions and their preparation, advantages, and challenges. Combining Gelucire with solid dispersion techniques provides a promising approach for improving drug delivery and therapeutic efficacy of poorly soluble drugs.

INTRODUCTION: An excipient is a substance that is used to transport a medication for administration. Pharmaceutical formulations often include polymers to help with processing of drug delivery systems, maintain, help with, or improve drug stability and bioavailability or patient acceptance, help with product identification, or enhance other aspects of the drug's overall safety, efficacy, or delivery during storage or use [1]. Due to their inadequate solubilization in digestive fluids, poorly water-soluble medications provide substantial obstacles during the creation of drug formulation.

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It is crucial to improve the solubility of poorly water-soluble drugs in order to increase their bioavailability. Currently, several methods are being employed to solve this issue [2]. To increase the medication substance's bioavailability, one method is to disperse it in a surface-active carrier; this process is referred to as solid dispersion. Surface active compounds have been used in solid dispersion alone or in conjunction with polymeric material throughout the past few years [3].

Suspending agents, wetting agents, emulsifiers, detergents, anti-foam chemicals, *etc*. are all considered surfactants. Surfactants are used in solid dispersion to increase physical stability as well as the rate at which poorly soluble drugs dissolve. Due to their amphiphilic nature, surfactants help hydrophobic pharmaceuticals become physically miscible. They also inhibit drug recrystallization, increase wettability, and prevent drug precipitation in aqueous media.

Gelucire (specifically, Gelucire 44/14) is an amphiphilic surfactant that is frequently used for solid dispersions. Poorly soluble medications have been shown to dissolve more quickly when added to Gelucires, which frequently results in increased drug bioavailability. They can be used in a wide range of oral and topical formulations [4]. Oral formulations can be used to increase an active pharmaceutical ingredient's (API) solubility and bioavailability, sustain release, mask taste, and protect API against air, light, and humidity. Gelucire is used in topical formulations to stabilise creams, lotions, and gels as well as thicken and improve medication penetration into the skin [1]. Fast/immediate/rapid release formulations often include Gelucire that exclusively contains PEG esters. In the creation of sustained release formulations, gelucire that only contains glycerides or a combination of glycerides and PEG esters is used [5, 6].

In order to boost oral bioavailability and solubilize weakly water-soluble APIs, Gelucire is a non-ionic water-dispersible surfactant for lipid-based formulations forms a fine dispersion, or microemulsion, by self-emulsifying in aqueous environments (SMEDDS) [7].

The two primary functions are to improve bioavailability and to swell poorly soluble APIs. Self-emulsifies into a coarse emulsion in aqueous fluid in a single excipient formulation system LFCS Type III (SMEDDS). medication release modification. In melt processes, lipid binder. Toxicological data and usage history of authorised pharmaceutical items serve as indicators of use safety [8].

In controlled-release matrices, gelucires are inert, semisolid, waxy, nonionic, amphiphilic excipients that are frequently utilised to enhance the physicochemical properties of drugs. Gelucires are blends of fatty acid polyethylene glycol esters and mono-, di-, and triglycerides. Glycerides and PEG, these two ingredients give the vehicle hydrophobic and hydrophilic characteristics. It is categorised as laurylmacrogolglycerides in the European Pharmacopoeia and as laurylpolyoxyglycerides in the US Pharmacopoeia [9]. By creating hydrogen bonds with the active ingredient, Gelucire speeds up the process of drug release and creates stable solids of amorphous drugs in the form of microparticles.

Types of Gelucire:

Gelucire 50/13 (Stearoyl Macrogol–32 Glyceride): This consists of mono- and di-fatty acid esters and polyethylene glycol glycerides. Palmitic and stearic acids are among the fatty acids found. Alcoholysis/Esterification is the synthesis method used, while PEG 1500 and hydrogenated palm oil are the starting materials. Its melting point ranges from 46 to 51ºC, and its HLB value is 11. It is a granular, semi-solid excipient that is known to improve the solubility of APIs that are not sufficiently soluble. It continues to be a favoured ingredient when creating capsules and is used in a range of formulation techniques (granules and tablets). When utilised in granulation, it provides a profile of immediate release due to its high HLB. It serves a number of purposes, including lubricant, solubilizer, sustain release agent, flavour masking, and bioavailability augmentation [7].

USP Name: Stearoyl polyoxyl-32 glycerides

Chemical Description: Consists of mono, di- and triglycerides and PEG-32 (MW 1500) mono- and diesters of palmitic (C16) and stearic (C18) acids.

CMC (mg/L, 25ºC): 100

Example: Solubility enhancement and physicochemical characterization of carvedilol solid dispersion with Gelucire 50/13.

(The SDs of carvedilol physical mixture and pure drug in Gelucire 50/13 were prepared and their dissolution parameters like mean dissolution time, dissolution efficiency and drug release rate, improved dissolution characteristics were compared. The physical mixture showed enhanced solubility and dissolution rate compared to pure drug). Preparation of Solid Dispersion of Everolimus in Gelucire 50/13 using Melt Granulation Technique for Enhanced Drug Release [10]. (The results of this study show that formulation of SD with Gelucire 50/13 using melt granulation technique may be a novel and promising approach for enhancement of the dissolution rate and oral absorption of the anti-cancer agent without the usage of an organic solvent).

Gelucire 44/14 (Lauroyl Macrogol Glyceride): It consists of a mixture of PEG - 1500 ester and long-chain fatty acid glyceryl. Lauric acid is a major fatty acid. Alcoholysis/Esterification is the synthetic process used, and PEG 1500 and hydrogenated palm oil are the starting materials. The melting point is claimed to be 42.5–47.5ºC, and the HLB value is [11]. It has been demonstrated that waxy solid excipients enhance the physicochemical characteristics of medicines [12].

USP Name: Lauroyl Polyoxyl-32 glycerides

Chemical Description: Consists of a small fraction of mono, di- and triglycerides and mainly PEG-32 (MW 1500) mono- and diesters of lauric acid (C12)

CMC (mg/L, 25ºC): 72±53 [13]

Example: Effect of Gelucire 44/14 on Fluconazole Solid Lipid Nanoparticles: Formulation, Optimization and in vitro Characterization

(Incorporation of GL in SLN not only reduced the particle size, improved the percent entrapment efficiency and increased the drug release, but also ensured the preparation of a stable formulation. In-vitro antifungal activity revealed significant decrease in Candida count with FZ SLN) [14].

Characterisation and solubility enhancement of etoricoxib in solid dispersion systems using lipid carriers gelucire 44/14.

Phase solubility study indicated a linear increment in the drug solubility with increase in polymer concentration. In-vitro drug dissolution indicates maximum drug release up to 99.84% from solid dispersion prepared by co-evaporation method [15].

Gelucire 48/16: A non-ionic pure surfactant for lipid-based formulation to solubilize and increase oral bioavailability of poorly soluble API. Forms micellar solution in aqueous media. Solubilizer for low log P APIs and bioavailability enhancer. Single excipient formulation system: self-emulsifies in aqueous fluid into micellar solution—LFCS Type IV. Use in melt processes (granulation, extrusion), granulation, and compression. Wetting agent. Safety of use is inferred by precedence of use in approved pharmaceutical products. The melting point claimed to be 46-50ºC, and HLB value is 12.

USP Name: Polyoxyl-32 stearate (type I) NF

Chemical Description: Consists of PEG-32 (MW 1500) esters of palmitic (C16) and stearic (C18) acids

CMC (mg/L, 25ºC): 153±31 [16]

Example:

Gelucire 59/14: The melting point claimed to be 57-62ºC, and HLB value is 14±1.

USP Name: Mixture of Lauroyl Polyoxyl-32 glycerides and PEG 6000

Chemical Description: Consists of a small fraction of mono, di- and triglycerides and mainly PEG-32 (MW 1500) mono- and diesters of lauric acid (C12) and of PEG-150 (MW 6000).

CMC (mg/L, 25ºC): 40 [17]

Gelucire 43/01: Highly hydrophobic lipid, Provides release retarding properties and floating behavior Matrix-forming agent for protection of APIs sensitive to oxidation, humidity, or light. Consistency agent in oral and topical formulations. Safety of use is inferred by precedence of use in approved pharmaceutical products. The melting point claimed to be 42-46ºC and HLB value is 1.

USP NF Name: Hard fat

Chemical Description: Consists of mono-, di- and triglyceride esters of fatty acids (C8 to C18), the triester fraction being predominant [18].

Gelucire 39/01: It is semisynthetic glycerides. It is a waxy solid, extremely hydrophobic due to the absence of PEG esters, which in turn provides release regarding ability Gelucire 39/01 is a carrier for oral formulations and specifically for hard or soft gelatin dosage forms. Used in the formulations as excipient, carrier, vehicle, and consistency agent. The melting point was claimed to be 39, and HLB value is 01.

Gelucire 54/02: Hydrophobic in nature, used in preparation of sustained release formulations and drug release is primarily controlled by diffusion. The melting point was claimed to be 54, and HLB value is 02.

Gelucire 33/01: Hydrophobic in nature, used in preparation of sustained release formulations and drug release is primarily controlled by diffusion. The melting point was claimed to be 33, and HLB value is 01 [2-16]. Examples of Gelucires is listed in the **Table 1.**

TABLE 1: EXAMPLES OF GELUCIRES

S. no.	Substance	Excipient Categories	Chemical Name
1	Gelucire50/13	Fat, oils excipient, Bioavailability augmenter, controlled release agent Stearoyl macrogol-32 glyceride 2 Gelucire 50/02 Fat oils drug carrier'	Stearoyl macrogol
2	Gelucire 50/02	Fat oils drug carrier's excipient	Saturated polyglycolized glycerides
3	Gelucire 55/18, Gelucire 44/14	Polyethylene glycols drug carriersPolyethylene glycols, Solubilizer, emulsifier, bioavailability enhance	Lauryl Macrogol glycerides
4	Gelucire 43/01	Excipient, fatting and consistency building agent	Glycerol esters of saturated C12-C18 fatty acids
5	Gelucire 33/01	Excipient, antioxidant, carrier vehicle	Glycerol esters of saturated C8-C18 fatty acids.
6	Gelucire 37/01	Excipient	Saturated polyglucolized glycerides
7	Gelucire39/01	Excipient, antioxidant, fatting agent, consistency building agent	Glycerol esters of saturated C12-C18 fatty acids
8	Gelucire 43/01	Excipient, fatting agent, consistency building agent	Glycerol esters of saturated C12-C18 fatty acid
9	Gelucire 53/10	Excipient	PEG-32 glyceryl stearate
10	Gelucire 62/02	Waxy material for melt processing method	Saturated polyglycolized glycerides

Characteristics and Applications of Gelucire in the Improvement of Dosage form Performance:

Hydration Behaviour of Gelucire: Svensson A. *et al*: studied the hydration behaviour of Gelucire 44/14, a commonly used pharmaceutical excipient with both water-loving (hydrophilic) and fat-loving (lipophilic) properties. They explored how it reacts to moisture in two ways: by exposing it to humid air and by directly adding water. They found that the different components of Gelucire absorb water in a specific order glycerol absorbs the most, followed by polyethylene glycol (PEG), PEG esters, and lastly glycerides like trilaurin. When small amounts of water are added, the PEG esters form structured gel-like phases (hexagonal and cubic mesophases), while Gelucire 44/14 forms a lamellar structure that melts at around 30°C. When the water content goes above 5%, all crystalline structures melt at body temperature, turning the mixture into a smooth liquid. This behaviour is important in medicine design because certain gel phases can slow down how the drug is released in the body. By controlling the composition of Gelucire, formulators can avoid unwanted gel formation and ensure the drug dissolves and acts properly after administration. As a result, the creation of amphiphilic excipients can be optimised to prevent the development of mesophases that prevent excipient breakdown at body temperature [19].

Hadri M. *et al*: focused on Gelucire 50/13, another amphiphilic excipient widely used in making sustained-release drug formulations. They studied how its molecular structure changes when water content increases from 0% to 80%, using advanced techniques like FTIR and Raman spectroscopy. As more water was added, Gelucire 50/13 underwent clear structural changes. It started with a bicontinuous structure where water and fat components are evenly distributed and gradually shifted to micellar structures, where water-loving parts form small circular clusters. These structural transitions are directly linked to how the excipient performs in drug release. Understanding these changes helps in designing more effective slow-release medicines, ensuring the active ingredient is released steadily over time in the body [20].

Solution Phase Stability by Using Gelucire: Ren *et al.* studied the chemical stability of rabeprazole sodium, a drug that easily breaks down in the digestive tract. They tested the drug in a fluid that mimics the environment of the small intestine (pH 6.8), mixing it with various safe ingredients known as GRAS-listed excipients including Gelucire 44/14, Brij® 58, Poloxamer 188, Cremophor RH40, and PEG 6000. The researchers incubated the mixtures at two temperatures (37°C and 60°C) and used HPLC to measure how much of the drug and its main breakdown product (thioether-

rabeprazole) remained over time. They found that rabeprazole breaks down following first-order kinetics, with faster degradation at higher temperatures. However, the addition of excipients helped improve the drug's stability. Among them, Brij® 58 showed the best stabilizing effect, significantly lowering the rate of degradation. This improvement is due to the way these excipients, including Gelucire, form micelles (tiny carriers) that protect the drug and balance between water- and fat-loving properties (HLB values. For instance, the k values of Brij®58 dropped to 0.22 and 0.53 h 1 at 37 and 60 °C, respectively. Additionally, formulations with adequate rabeprazole excipients would increase the stability and digestive tract bioavailability of the medication.

Damian *et al*: examined how storage conditions affect the stability of drug formulations made using solid dispersions, including those with Gelucire 44/14. They prepared these dispersions using solvent and melting methods and stored them at temperatures ranging from 4°C to 250°C. Tools like DSC, XRD, and dissolution studies were used to check physical and chemical changes. For dispersions made with PVPK30, no recrystallization of the drug occurred, showing good stability. However, in the case of formulations using PEG 6000 and Gelucire 44/14, the energy required to melt the solid (enthalpy of fusion) increased with higher storage temperatures, especially up to 250°C. Depending on the length of storage, the dissolution of UC-781 in all solid dispersions may be caused by changes in the physical condition of the supports rather than by the medication [21].

Oral Bioavailability Enhancement by Using Gelucire: Shaker *et al*. Gelucire, a hydrophilic carrier with both lipid and surfactant properties, has shown great potential in enhancing drug delivery performance. In the formulation of hard gelatin capsules containing atorvastatin (Atv), a poorly water-soluble drug, a binary system using Gelucire 50/13 and Gelucire 44/14 was developed to improve its solubility and absorption. These forms of Gelucire helped convert the drug into a more soluble state, resulting in a significant increase in the rate of dissolution and oral bioavailability. Characterization studies, including *in-vitro* dissolution testing, *in-vivo* pharmacokinetic studies, Differential Scanning Calorimetry (DSC), X-ray Powder Diffraction (XRD), and Fourier-Transform Infrared Spectroscopy (FTIR), confirmed that Gelucire improved the physicochemical properties of atorvastatin by maintaining it in an amorphous, more bioavailability.

Increased Drug Release: Sanjeevani S. Deshkar: Gelucire has proven to be a versatile excipient in enhancing drug release and absorption in various dosage forms. In a study by Sanjeevani S. Deshkar, Gelucire 44/14 (GL) was used along with glyceryl monostearate (GMS) to prepare solid lipid nanoparticles (SLNs) of a drug called FZ SLN using the microemulsion method. The concentration of Gelucire played a key role in improving the formulation. The optimized SLN formulation had a particle size of 143 nm, PDI of 0.38, drug entrapment efficiency of 75.2%, and 84.9% of the drug was released within 8 hours. The addition of Gelucire not only stabilized the nanoparticles but also reduced the particle size, enhanced drug entrapment, and significantly increased drug release, making it highly effective for controlled delivery [22].

Immediate Release: Jang *et al*: developed a solid dispersion (SD) system using Gelucire 50/13 (GLC 50/13) to improve the immediate release of everolimus (EVR), an mTOR inhibitor. The SD was created using the melt granulation method, which did not require any organic solvents, simplifying the manufacturing process. The optimized formulation, made with EVR, Gelucire 50/13, and microcrystalline cellulose at a ratio of 1:5:10, showed a significantly faster dissolution rate compared to both the pure drug and the commercial product (Afinitor®). Over 80% of the drug was released within just 10 minutes, demonstrating the potential of Gelucire 50/13 in creating tablets with rapid onset of action and enhanced oral absorption. Thus, Gelucire's ability to improve drug solubility, release rate, and bioavailability, making it a valuable tool in both controlled and immediate-release formulations.

Solubility Enhancement: Raja Hemanth Kumar P *et al*: Gelucire has been widely studied for its ability to enhance the solubility and dissolution rate of poorly water-soluble drugs, which is essential

for improving their oral bioavailability. In a study by Raja Hemanth Kumar P *et al.,* Gelucire 50/13 was used to prepare solid dispersions (SDs) of carvedilol, a poorly soluble drug. It was observed that as the concentration of Gelucire increased, the solubility of carvedilol also increased in a linear fashion, confirming a type A(L) solubility profile. Characterization of the solid dispersions using scanning electron microscopy and differential scanning calorimetry (DSC) revealed that the drug had changed from its original crystalline form to an amorphous form, which is typically more soluble. Fourier-transform infrared spectroscopy (FTIR) further confirmed that there were no chemical interactions between the drug and Gelucire, supporting the physical stability of the formulation.

The solid dispersions showed significantly improved dissolution parameters such as mean dissolution time, dissolution efficiency, and drug release rate when compared to the pure drug or physical mixtures. These improvements are particularly important for drugs classified as BCS (Biopharmaceutics Classification System) Class II, which are poorly soluble but highly permeable. For such drugs, solubility and dissolution rate are the main barriers to effective absorption in the gastrointestinal tract. Enhancing these properties using carriers like Gelucire can lead to better bioavailability and reduced side effects.

Based on information in the public domain, the World Health Organisation (WHO) gave a BCS classification to its model list of essential medicines. 61 of the 130 medications for oral administration on the WHO list could be categorised with certainty. These medications fall under class I for 84%, class II for 17%, class III for 39%, and class IV for 10%. The bioavailability, which ultimately depends on solubility, is crucial for class II and class IV drugs. Therefore, in order to successfully manufacture medications with low aqueous solubility into bioavailable medicinal products, a deeper understanding of the dissolution and absorption behaviour of those drugs is necessary.

CONCLUSION: Gelucire's are versatile excipients that play a key role in improving drug delivery. Gelucire is the family of vehicle derived from mixtures of mono, di and triglycerides with PEG esters of fatty acids. It is available in wide range of HLB values starting with 01-16. Their ability to enhance solubility, stability, and bioavailability makes them valuable in the development of both immediate and controlled-release drug formulations. Different types of Gelucire offer a range of hydrophilic and hydrophobic properties, allowing them to be used in various oral and topical drug products. Because of their proven safety, ease of processing, and effectiveness, Gelucire's are important tools in addressing the challenges faced with poorly soluble drugs, especially those in BCS Class II and IV. Hence, the review presented in this article can serve as a ready reference for researchers using various types of Gelucire as a carrier to enhance the solubility of poorly water-soluble drugs.

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