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A Review on Enhancement of Solubility, Dissolution Rate and Bioavailability of BCS Class-II Drugs

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ABSTRACT

Solubility is how well a solid dissolves in a liquid to make a uniform mixture, and it directly affects a drug's bioavailability-how much of the drug actually reaches the bloodstream to produce an effect. Many new drugs are lipophilic and poorly water-soluble, with over 40% facing this issue, which can limit their success. To address this, researchers improve solubility and dissolution using methods like salt formation, co-solvents, surfactants, solid dispersions, Improve bioavailability of poorly water-soluble, lipophilic drugs by matching mechanism to limitation: use salt formation (for ionizables), surfactants/wetting agents, co-solvents or cyclodextrins (for neutral), solid dispersions (reduce lattice energy, sustain supersaturation), and nanocrystals .

KEYWORDS

Solubility, solid dispersion, Henderson-Hasselbalch , salt formation, Bioavilability improvement.

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INTRODUCTION

'Solubility' refers to maximum quantity of solute that can be dissolved in given amount of solvent. It can be defined by both a quantitative and a qualitative definition. Quantitatively it is defined as the concentration of the solute in a saturated solution under a specified temperature. Qualitatively it can be defined as the spontaneous interaction of at least two substances, in which the solute forms a homogenous molecular dispersion with the solvent. A saturated solution is one in which the solute is in equilibrium with the solvent. The solubility of a drug can be expressed based on its various concentrations such as molarity, parts, percentage, molality, volume. The compendial books use the parts of solvents required to dissolve one part of solute (Table 1)[1,2,3].

Table 1: Classification system for drugs – Solubility

BIOPHARMACEUTICAL CLASSIFICATION SYSTEM FOR DRUG

CLASS	SOLUBILITY	PERMEABILITY	EXAMPLES
Class I	High	High	Metoprolol , Propranolol
Class II	Low	High	Nifedipine, naproxen
Class III	High	Low	Cimitidine, Metformin
Class IV	Low	Low	Taxol, Clorthiazole

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MATERIALS AND METHODS

1. To conduct a systematic review of various interventions designed to improve solubility, dissolution rate and, bioavailability of BCSClass II drugs; comparing methods, finding gaps, and providing recommendations for future studies.

2. Search strategy: Searching Pubmed/Medline, Scopus, Web of Science, and Google Scholar for studies (last 20 years) or older studies as needed using keywords and Boolean strings such as: "BCS Class II "OR" poorly soluble, solubility enhancement "OR" bioavailability" and methods terms (e.g. "nanoparticles" OR nanosuspension" OR "solid dispersion" OR "cyclodextrin" OR micronization "OR" lipid-based "O "cocrystal"). Articles in English including either article, review, in-vitro or in-vivo studies, or articles for patent information.

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RESULTS

BCS CLASSIFICATION

Guidelines for the Biopharmaceutical Classification System1 (BCS) were made available by the US Food and Drug Administration (FDA), to help improve the efficiency of drug product development process. According to which drugs are classified into four major classes based on their solubility and permeability.

Class 1: A drug that has both high solubility and high permeability.

Examples: Propranolol. Metoprolol, Diltiazem. Verapamil.

Class II: A drug that has high permeability and low solubility.

Examples: Ketoconazole, Mefenamic acid, Nifedipine, Nicardipine, Felodipine, Piroxicam.

Class III: A drug that has low permeability and high solubility.

Examples: Acyclovir, Neomycin B, Captopril, Enalaprilate, Alendronate

Class IV: A drug that has low permeability and low solubility.

Examples: Chlorthiazide, Furosemide, Tobramycin.[7,8,9,10]

Technique of solubility Enhancement

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- Particle size reduction
    - Micronionization
    - Nanosuspension
- Supercritical fluid process
- Modification of crystal habit
- Drug dispersion in carrier
    - The fusion melt method
    - Solvent method
- Spray drying method
- Co-Grinding method
- Lyophilization freeze drying method
- Change of pH
- Prodrug

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- Salt formation

- CO-Crystallization

- Co solvent

- Hydrotropy

- Miscellaneous method

    - Supercritical fluid process[SCF]

    - Micellar solubilization

    - Solubilization by surfectant

    - Microemulsion

A. Particle Size Reduction

1.Micronization

Micronization is a specialized milling technique for reducing particle size to the micron or sub-micron range. It is especially relevant for the pharmaceutical field; poorly soluble drugs can significantly improve their bioavailability by micronization of drug particles to the micrometer range. Micronization can be accomplished with technologies such as air jet milling, spiral jet milling, and bead milling. Air jet milling occurs when compressed air or gas creates a high-velocity stream of air that collides with and fractures the drug particles to the desired size.[12,13]

2.Nanosuspension

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Nanosuspensions are colloidal dispersion of pure drug particles, sub-micron in size, and stabilised by surfactants. Nanosuspensions technology resolved the issue of drug used which were poorly aqueous soluble and had lower bioavailability. Nanosuspension technology can improvise and enhance stability and bioavailability of drugs.

Nanosuspensions can be prepared using wet mill, high pressure homogenizer, emulsion, solvent evaporation, melt emulsification method and supercritical fluid techniques.Nanosuspensions can be delivered via oral, parenteral, pulmonary and ocular routes.[14]

B. Supercritical fluid process

Supercritical fluid method: SCF - supercritical fluid is fluid which is a single fluid above the critical temperature and pressure. Above the critical condition, the SCF demonstrates gas and liquid properties. It is a greener, safe and efficient process. The low operating conditions (temperature and pressure) results in SCFs for pharmaceutical research to disrupt energy and time constraint. SCFs near- critical conditions are highly compressible, requiring moderate changes in pressure to lead to major changes in the density and mass transport properties of the fluid which mainly determines its solvent ability. Once drug particles are solubilised within SCF conditions, they may be re-crystallised at much reduced particle sizes.[15]

C. Modifications of the crystal habits

Polymorphism is the capability of anelement or compound to crystallize in more than one crystalline form. Different polymorphs of drugs are chemically identical, but they exhibit different physicochemical properties including melting point texture, solubility, density.stability.Similarly amorphous form of drugs is always more suited than crystalline forms to higher energy associated and increase in surface area.Order for dissolution of different solid forms of drugs is

Amorphous > Metastable polymorphs > stable polymorphs

D. Drug dispersion in carriers

Sekiguchi and Obi were the first ones in 1961 introduce solid dispersion to enhance dissolution and oral absoprtion of poorly water soluble drugs. In solid dispersion the poorly soluble drug is dispersed in a highly soluble solid hydrophilic matrix, which enhances the dissolution of drug and can yield eutectics and/or solid solutions.[15,16,17,18,19,20,21]

Types of solid dispersion

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First generation solid dispersions:

First generation solid dispersions achieved faster drug release through a combination of

eutectic mixtures and molecular dispersions. An important drawback of this formulation is that the crystalline solid formulation may not release its drug quickly.Crystalline carrier examples include urea, sugars and organic acids [21].

Second generation solid dispersion:

When solid dispersion employed an amorphous carrier, which allows for an even more rapid drug release; fully synthetic polymers have included povidone (PVP), polyethyleneglycols (PEG), polymethacrylates, and natural polymers that rely on cellulose derivatives (e.g. hydroxypropyl methylcellulose (HPMC) or ethylcellulose), and or some starch derivatives, (e.g. cyclodextrins).

Third generation solid dispersion:

properties. Surface active carriers reduce the recrystallization of the drug and thus, improve solubility. Examples of synthetic surfactant self-emulsifying carriers include poloxamer 408, Tween 80, Gelucire 44/14

1.Melting method / fusion method

As previously noted, the fusion method is sometimes referred to as the melting method, which is only correct if the physical mixture itself are crystalline. Thus, a better term is fusion method, from the perspective of scientific terminology. Regardless, the combination physical mixture of a drug and a water soluble carrier, either crystalline or non, makes the fusion method or melting method appropriate.

2.The solvent method

In this technique, both the active drug and the carrier must be made soluble in a common solvent, and then the solvent will be removed under vacuum to produce a solid solution.This allowed to produce a solid solution of the very lipophilic R-carotene utilizing a very water soluble carrier polyvinyl pyrrolidone. A multitude of investigators have studied solid dispersions of Meloxicam, Nimesulide, and Naproxen using solvent evaporation method. This method increases solubility and stabilization of solid dispersions of hydrophobic drugs. The major advantage of solvent method is that thermal decomposition of drugs or carriers could be avoided an a result of the low temperature for the evaporation of the organic solvent. Example of some of solvent used included Acetic acid, Acetone, 1 -Butanol, 2-Butanol, Dimethyl

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sulfoxide, Ethanol and Ethyl acetate[22]

E. Spray drying technique

The drug is dissolved in some suitable solvent and the stoichiometric amount of carrier material, like a cyclodextrin, dissolved in water to a correct stoichiometric composition is prepared. The solutions then mixed together using ultrasonication or other suitable technique to allow the solutions to combine and produce a clear solution, which is spray dried using a spray dryer. An example includes the solubility of Glipizide increases with this process.[23]

F. Complexation

Inclusion complexes are formed when a nonpolar molecule, or the nonpolar region, of one compound enters into the cavity of the donor molecule of a polar nature.Inclusion complexes come about through the entrapment of a nonpolar subsection of one molecule, referred to as guest, into an open cavity of another molecule or group of molecules, known as host. Cyclodextrins are commonly used host molecules, which form following enzymatic degradation of starch by cyclodextrin-glycosyltransferase (CGT) and result in cyclic oligomers, cyclodextrins (CDs). These are non-reducing, crystalline, water soluble, cyclicoligosaccharides made of glucose monomers stacked in a donut shaped ring, which to create a hydrophobic cavity surrounded by a hydrophilic outer surface.The three naturally occurring CDs these includes α-Cyclodextrin, β-Cyclodextrin, and γ- Cyclodextr. [24,25]

G. Drying by Spraying:

Spray-drying has been among the top three most widely used methods to remove solvents

in the creation of solid dispersions. The large surface area of droplets increases the rate of the solvent, thus forming a solid dispersion in a matter of seconds. This fast process may Prevent phase separation from occurring.[25]

H. Co-grinding method

A physical mixture of carrier and drug is blended for some time at a constant mixer speed. After mixing, the mixture is transferred into the chamber of a vibration ball mill in which pre- mixed steel balls are added. The powder mix is ground, then a sample is transferred and stored at room temperature in a glass vial with screw cap until needed. For example, solid dispersions of mannitol and Chlordiazepoxide could be produced in this manner. [26,27,28]

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I. Lyophilization / Freeze-drying technique:

Lyophilization (or freeze-drying) is a method that involves molecular mixing of drug and solvent in the same solvent, and could be described as an alternate to solvent evaporation26-29.Lyophilization is very dependent upon the unique properties of water, as it serves the role ofa solvent, gas, diluent, plasticizer, and stabilizer. This method involves the removal of thesolvent system from the solution by first freezing it, and then drying the solution which contains both drug and Cyclodextrin, using reduced pressure[29,30].

J.Change of pH

Modification of microenvironment pH to change the ionization behavior is the simplest and perhaps most well-established method for enhancing the water solubility of ionizable compounds. As per pHpartition hypothesis and Handerson - Hasselbalch equation, ionization of a compound is dependent on pH of media and pKa of drug. The change in the ionic milieu can also resultsinin situ salt formation. However, this salt formation is unfeasible for nonionized compounds.The formed salts may also converse to respective acid or base forms in gastrointestinal tract.

K.Salt-Formation

Saltformationstrategiesareisusedtodevelopmentofthesolubilityanddissolutionofdrug.this approach is for the method of any response of various drug or chemical response. salt is formed with the drug is ionized shape It bioavailabilityPurification and manufacturability of the drug.Salt formation has been a method for several. intervals to better solubility.Ex.Aspirin,Theophylline,Barbituratesetc.

L. Co-crystallization

Revamping molecular interactions is a reflective and reliable alternative to improve drug properties. Co-crystallization can be defined as "Formation of a multicomponent crystal between two compounds that are solid under ambient conditions, where at least one component is an ion or molecule." Co-crystallization has made overcoming the various limitations (physical, chemical, or physiological) of active pharmaceutical ingredients (API) possible. [31]

M. Co-solvent

It is already well documented that the introduction of a co-solvent (organic) to water can drastically alter drug solubility. Electrolytes that are weak and nonionic molecules have low solubility in water; however, by the introduction of a co-solvent (a water-miscible solvent in which the drug has higher

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solubility), the solubility of a poorly soluble drug can be enhanced. These formulations are commonly referred to as co-solvent formulations or solvent blending. Co-solvent formulations can be delivered orally or parenterally with poorly soluble drugs. Most co-solvents contain both hydrogen bond donor and acceptor groups (amines, acids, alcohols, etc) and have small hydrocarbon domains. Their contributions of hydrogen bonding in the hydrophilic regions will confirm miscibility with water, while their hydrophobic domains disrupt the water's hydrogen bonding network. This disruption will change the intermolecular forces between water molecules and thus reduce the overall intermolecular attractive forces of water. [32]

N.Hydrotropy

Hydrotropy is an intriguing solubilization phenomenon, in which the addition of a large amount of a second solute produces an increase in the aqueous solubility of another solute. Concentrated aqueous hydrotropic aqueous solutions, such as sodium benzoate, sodium aciculate, urca, nicotinamide, sodium citrate and sodium acetate, have been found to increase the aqueous solubility of numerous poorly water-soluble drugs. Hydrotropic agents are ionic organic salts . [32]

Advantages of hydrotropy

1. In the hydrotropy method the solvent character is independent of pH, has high selectivity and does not require emulsification.

2. In this method you simply mixed the drug, in powder form, with the hydrotropes in water.

It does not require chemical modification of hydrophobic drugs, the use of organic solvents or special equipment.

O. Miscellaneous method Supercritical fluid process (SCF)

The number of applications and technologies associated with SCFs has also increased explosively. For more than a century, SCFs (supercritical fluids) have been recognized to be capable of dissolving nonvolatile solvents, and carbon dioxide, the most utilized supercritical fluid, critical point is low and overall is safe, environmentally acceptable, and cost effective. The low operational conditions (pressure and temperature) associated with SCFs make them attractive paradigms for pharmaceutical research. A supercritical fluid is defined as a fluid existing only as a single phase above its critical temperature (Tc) and pressure (Pc). SCFs have properties advantageous to product processing because their characteristics are intermediate to those of a pure liquid and gas. Furthermore,characteristics of SCFs, such as density,

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transport properties (diffusivity and viscosity), as well as other physical characterizing characteristics (polarity, dielectric constant, etc.), can change significantly with a small change in operational temperature, pressure, or both, around the critical point. Thus, it is achievable to fine-tune a unique combination of properties to some extent for any particular desired application. Micellar solubilization By utilizing surfactants to enhance the dissolution behavior of poorly water soluble drug products is also a behavior that has been demonstrated in practice to work. Surfactants can reduce surface tension as well as improve a hydrophobic drug's dissolution behavior in an aqueous medium and can also be utilized to stabilize drug suspensions as well.

P.Micellar solubilization

By using surfactants to improve the dissolution performance of poorly water soluble drug products has also been effectively employed. Surfactants can decrease surface tension and improve the dissolution of hydrophobic drugs in aqueous medium. as well as used to stabilize drug suspensions.when the concentration of surfactants exceed their criticals micelle concentration (CMC, which is in the range of 0.05-0.10% for most surfactants), micelle development occurs, entrapping the drugs inside the micelles. This process is known as micellization and usually results in improved solubility of poorly soluble drugs. Commonly used non-ionic surfactants include polysorbates, polyoxy ethylated castor oil,polyoxy ethylated glycerides, lauroyl macroglycerides and mono- and di- fatty acid esters of low molecular weight polyethylene glycols. Surfactants are also used to stabilize suspensionsand microemulsion into which drugs are liquified. [34,35]

1.Solubilization by surfactants

They can accumulate in the intramicellar hydrophobic core during the solubilization process. This solubilization is particularly important in industrial and natural processes.

2.Microemulsions

A microemulsion is a system that consists of an oil, hydrophilic surfactant, and hydrophilic solvent that liquifies a drug that is poorly soluble in water. It is optically clear, translucent, isotropic, and thermodynamically stable. Hydrophobic lipophile balance (HLB) and non-toxicity are the selection criteria for surfactants. The formulations self-emulsify when they come into contact with water, creating a very clear emulsion of tiny, uniform oil droplets that contain the poorly soluble drug.

3.Self-emulsifying drug delivery systems

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Employs the concept of in situ emulsion formation in the gastrointestinal tract. A precise mixture of oil, co-surfactant, surfactant, and one or more hydrophilic and co-solvents is prepared, and upon incorporation with aqueous solvent, it forms a clear, isotropic solution known as self-emulsifying drug delivery systems (SEDDS). Self-emulsifying drug delivery systems (SEDDS) and self- microemulsifying drug delivery systems (SMEDDS) solutions of oil and surfactant, in the presence of aqueous solvent, forms oil-in-water microemulsions. [39]

DISCUSSION

A drug's solubility is a key determinant of its bioavailability, therapeutic performance, and overallpharmacokinetics. Within the Biopharmaceutics Classification System, Class II compounds exhibit low solubility but high permeability, making their absorption primarily limited by the rate of dissolution rather than membrane transport. Consequently, strategies that enhance solubility and dissolution are critical for improving the oral bioavailability of these agents (Savjani et al., 2012).

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CONCLUSION

In conclusion, we state, Solubility is the most significant physical property of a drug for its oral bioavailability, development of a formulation for delivery as a dosage form or as a drug product, and for evaluative use of therapeutic efficiency and quantitative analysis. Selecting the appropriate method of solubility enhancement is the most critical to meeting the criteria of a suitable formulation, including a beneficial oral bioavailability, minimizing dosing frequency, improving patient compliance, and keeping production costs low. Numerous techniques can increase solubility, which may also increase the number of folds in solubility. A number of drugs are poorly soluble, and this solubility problem can affect their bioavailability, making solubility enhancement necessary. It is now possible to enhance the solubility of poorly soluble drugs using a number of techniques, as described.

ABBREVIATIONS

BCS-Biological classification system
SCF-Super critical fluid

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