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Review Article

Review On Liquisolid Compacts – An Approach To Enhance The Solubility Of Bcs Class Ii Drugs

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ABSTRACT

Liquisolid technique is one of the technique to improve the solubility of poorly water soluble drugs. Nearly 60 % of the newly developed drugs possess the problem of low oral bioavailability due to low aqueous solubility. One of the novel approaches to overcome this problem is liquisolid technique. This technique involves mixing the solution or suspension of drug with appropriate amount of carrier and coating material to form freely flowing compressible powder. This paper briefly describes about the various components of the liquisolid formulation and also specifies the evaluation parameters of the liquisolid compacts. This paper explains about Spireas theory for calculating appropriate amount of carrier and coating material to be incorporated in the liquisolid formulation. This paper also describes the various applications of the liquisolid technique including bioavailability enhancement, prolongation of drug release, improvement of photostability. As a whole, the liquisolid technique is considered as the effective method to improve the solubility of poorly water soluble drugs.

INTRODUCTION

Poor bioavailability is the major concern for many orally administered drugs. Oral bioavailability mainly depends on the solubility of these drugs in the intended dissolution medium. Dissolution is the rate limiting step for those drugs which comes under BCS Class II drugs (1). There are many approaches to improve the dissolution profile of many poorly soluble drugs. For example, solid dispersion, salt formation, micronization, complexation, etc. Each technique has its own merits and limitations. Micronization (2) is the commonly employed technique where reduction in particle size leads to increase in surface area, ultimately solubility also gets increased. Solid dispersion is the promising technique in the field of the solubility enhancement (3). One of the main limitation involved in this technique is that poor

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stability associated with the formulation upon storage.

Among these various approaches, liquisolid compacts is the novel approaches for improving the solubility of BCS class 2 drugs. This technique involves converting the liquid drug into compressible powder form with the aid of some excipients such as carrier material and coating material (4). The liquid drug get entrapped into the framework of carrier and coating material used to convert the powder into dry and compressible form. Apart from solubility enhancement, this is also promising method in the prolonging the release of the drug, minimizing the effect of the pH variation in the drug release and also increasing the photostability of photosensitive drugs (5).

COMPONENTS OF LIQUISOLID COMPACTS

Liquid vehicle

Liquid vehicle preferred should be non volatile and not highly viscous, water visible organic solvents. Commonly employed liquid vehicle includes PEG 200 and PEG 400, propylene glycol, polysorbate 20 and 80.(6) Solubility of many drugs in the selected liquid vehicle affe9cts the dissolution profile. If the solubility of drug in the solvent is high, then amount of carrier is needed to dissolve the drug will be reduced and thus weight of the tablet can be reduced significantly. Similarly if the solublity of drug is higher, F_M value i.e, fraction of molecularly dispersed drug also get increased.(7) Liquid vehicle should be chosen based on our specific needs. If we need to enhance the dissolution profile, solvents with higher ability to dissolve the drug must be chosen. Whereas if we need to prolong the release, solvents with less ability to dissolve the drug must be chosen.

Carrier material

Carrier material are highly porous material, mainly incorporated in liquisolid compacts to facilitate absorption.(8) If appropriate amount of solvent is added to the carrier material, they exhibit excellent flow as well as compression properties. Three different grades of microcrystalline cellulose are available and used as promising carriers for liquid solid system. They are MCC PH 101, MCC PH 102 and 200.(9) Among these three grades of MCC, MCC PH 101 was found to show better flow property and compressibility than other two grades. Since MCC PH 101 show higher dissolution rates, it is widely used as a carrier in liquisolid compact formulations.

Specific Surface Area (SSA) play a critical role in the selection of carrier for liquisolid compacts. Carrier with high SSA value posses high adsorption capacity. (10) Thus little amount of carrier is enough to formulate liquisolid compacts. Whereas if the carrier has low SSA value, the formulation need more amount of carrier and consequently tablet weight also gets increased. For formulating sustained release liquisolid compacts, polymers such as eudragit RL and RS are commonly added.(11) Fujicalin is a dibasic salt of calcium phosphate, which posses high SSA value of $40 m^2/g$ and subsequently high adsorption capacity. Another recently developed promising carrier is neusilin which is amorphous form of magnesium alumino metasilicate. It is available in eleven grades and also posses high SSA value upto 300 m^2/g. Several studies showed that neusilin posses seven times higher adsorption capacity, compared with avicel.

Coating material

Coating materials are mainly added to impart flow properties by adhering to the wet surface of the carrier material. Examples of Coating material includes aerosil, neusilin, silica , magnesium alumino mettalosilicate, calcium silicate, etc. They are usually coated on the exterior of the carrier material to improve the flow property and compressibility. They form dry, non adherent, freely flowing powder by covering the wet carrier material and make it to compressible powder.(12)

Neusilin has various advantages over other coating techniques such as aerosil, silica. Because neusilin has higher adsorption capacity, thus tablet weight has been reduced significantly.(13) It can be employed as both carrier and coating material in the formulation of liquid solid system.

Additives In addition to the above mentioned excipients, liquid solid formulation also includes various additives such as disintegrating agents , retarding agents etc. Disintegrating agents aid in break up of the tablets and allow fast disintegration. Commonly used disintegrating agents in the formulation of liquid solid system includes croscarmallose sodium, starch glycolate, low substituted hydroxypropyl cellulose etc.(14) Another promising material used in the liquisolid system includes polyvinyl pyrolidine which inhibits the crystal growth in the formulation. Liquisolid formulation containing PVP as a additive show better dissolution profile.(15) Retarding was usually added in the formulation to extend the release of the drug from liquisolid compacts. Commonly used retarding agents in the liquisolid system was HPMC.(16)

THEORY OF LIQUISOLID COMPACTS

Appropriate quantity of excipients should be incorporated into liquisolid compacts to attain better flow properties and compressibility. Despite the quantity of carrier and coating material, the amount of liquid medication also affect the flow properties and compressibility of the powder material. Only limited quantity of liquid medication should be incorporated into the liquisolid compacts. To obtain the acceptable flow property, Spireas introduced a mathematical model for determining required quantity of carrier and coating material by which liquisolid compacts with acceptable flowability and compressibility can be obtained.(17) The mathematical model proposed by Spireas involves 2 values based on the properties of the powder

(i) Φ – value termed as flowable retention potential, which means the maximum amount of the liquid vehicle that can be incorporated into bulk, thus maintaining acceptable flow property.

(ii) Ψ – value termed as compressible retention potential, which means the maximum amount of the liquid vehicle that can be incorporated into bulk, thus maintaining acceptable compressibility.

Pactisity is defined as maximum strength required to crush one gram of tablet, when compressed at high compression force. Optimum liquid load should be selected to obtain acceptable flow property and compressibility.(18) Liquid Load Factor (Lf) can be defined as amount of the liquid formulation divided by amount of the carrier material. $Lf = W/Q$

Where W and Q is defined as Weight of the liquid formulation and Carrier respectively. (19)

R (Excipient ratio) is defined as the weight of carrier divided by the weight of coating material. $R = Q/q$

Where Q and q are called amount of the carrier and coating material respectively.

Determination of **Lf**

i) For acceptable flow property

$$Lf = \Phi + \Phi/R$$

ii) For acceptable compressibility

$$Lf = \Psi + \Psi/R$$

Optimum Liquid load can be determined by using above mentioned formula. Appropriate quantities of carrier and coating material can be determined by using Liquid load factor. (20)

$$Q_0 = W/L_0$$

$$q_0 = Q_0/R$$

Where, Q_0 - required amount of carrier material

q_0 – required amount of coating material.

Mechanism by which liquisolid compacts increase drug release. (21)

(i) Increased drug surface area

Even though the selected non volatile solvent completely dissolves the drug particles, the drug is still present in powdered form. Surface area of liquisolid compacts is higher than that of directly compressible tablets. If the surface area gets increased, amount of drug that come in contact with the dissolution medium also gets increased. Drug release will be reduced, if more amount of undissolved drug present in the liquisolid compacts formulation. Whereas if the amount of molecularly dispersed drug increased, drug release will be increased.(22)

(ii) Increase in aqueous solubility

Minimum amount of liquid vehicle may be insufficient to completely dissolve or solubilize the drug in liquisolid compacts. To improve solubility of poorly soluble drugs at the interface between the powder surface and liquid carrier, sufficient quantity of solvents that diffuse out of liquisolid compact particle is necessary. If the co-solvent, to increase the solubility of drug is added, small amount of liquid carrier is enough to dissolve the drug.(23)

(iii) Enhanced wetting properties

In liquid-solid system, wettability can be determined by measuring the contact angle. Non volatile solvent decreases the interfacial tension between powder surface and medium, whereby increasing the wetting property of the drug particles. When compared to conventional tablets, liquisolid compacts posses low contact angle, thus increased wettability. In this LS system, the liquid vehicle employed also acts as a surfactants by decreasing the contact angle.(24)

GENERAL PREPARATION PROCEDURE

Required quantities of the drug and liquid vehicle are weighed and mixed together, if necessary heating or sonication is provided for complete solubilization. Remaining excipients such as carrier, coating material, additives are mixed with drug solution or suspension. Three major steps of mixing process proposed by Spireas and Bolton includes the following, (25)

- The drug solution or the suspension is poured on to the carrier material (required quantity) and mixed at the speed of one revolution/ sec for nearly 1 minute to form a homogeneous mixture of drug in carrier. After homogeneous mixture is formed, the coating material is added and blended thoroughly.
- The resultant mixture is spread on the surface of the mortar uniformly and to allow complete adsorption of drug into the carrier and coating material.
- Finally disintegrating agent is added to above mixture and thoroughly blended to obtain a liquid solid system, which was either compressed or encapsulated to form liquid solid compacts. (26)

EVALUATION PARAMETERS

Pre compression parameters (27)

X-Ray Diffraction Studies

Crystalline structure of the drug, the excipients, mixture of drug and excipients can be determined with the help of X- Ray Diffraction studies. If the drug in the liquisolid system is in the completely solubilized state, it does not show any characteristics peak in the XRD studies. Consequently if the drug is in solubilized form, solubility and dissolution rate also enhanced.(28,29)

SEM (Scanning Electronic Microscopy)

Scanning Electron Microscopy was performed to study the morphological characters of the drug and the carriers used. If any crystals of drug are present, it indicates that drug is not in completely dissolved form.(30)

Differential Scanning Calorimetry (DSC)

DSC is usually done to analyse the thermal behaviour of the active drug and the carrier material used in the liquisolid compacts. Any interaction between the API and excipients used can be found by DSC. This DSC Thermogram

does not show any additional characteristics peak, if the drug is in solution form.

Flow Property

The powder material which is to be compressed into liquisolid compacts, should possess adequate and uniform flow. Flow property can be determined by estimating angle of repose of the powder material, carr's index, Hausner's ratio, etc. Funnel method was used to calculate the angle of repose, which involves estimating the height and radius of the cone formed, when the powder is allowed to flow through the funnel. Carr's index and Hausner's ratio was estimated by determined bulk density and tapped density of the powder.(31)

Post compression evaluation

Weight variation

Twenty tablets were selected in a random manner and weighed individually. Then the average weight of all the 20 tablets was found and then compared with the weight of the individual tablet to determine the weight variation among the compressed tablets.(32)

Friablility

Roche friabilator was used to determine the friablility of prepared liquisolid compacts. Six liquisolid compacts was weighed and introduced into the friabilator and allowed to rotate at 25 rpm for 4 minutes. Then they are removed, dedusted and rewieghed. Friablility of the prepared liquisolid compacts was determined by

Friablility = (Wa- Wb) / Wa × 100

Whereas Wa indicates initial weight and Wb indicates final weight of the prepared tablets.

if the determined value lies below 1%, then, the prepared tablets are less friable during transportation.(33)

Hardness

"Monsanto hardness tester" was used to estimate the hardness of the prepared liquisolid compacts. It is defined as the force required to break the tablets and denoted as kg. The optimum hardness range for tablets 4-6 kg.

Disintegration test

USP disintegration apparatus (Basket type) was used to perform the disintegration test for the prepared tablets. 6 tablets are taken and placed in the basket, which contains water as a disintegration medium maintained at 37 ^{o}C. The apparatus was made to run and time taken for the complete disintegration was noted. (34)

Dissolution test

USP type II apparatus was used for testing the dissolution profile of the formulated liquisolid compacts. 6 tablets were taken and placed in each tube of the dissolution apparatus . Dissolution medium used in the study was phosphate buffer of pH 7.4 (900 ml) and temperature of the dissolution medium was maintained at 37^{o}C. At a fixed interval, five ml of the sample was withdrawn from each of the tube (which was replaced with fresh medium) and filtered. The filtered solution was analysed under UV and absorbance was studied. (35)

APPLICATIONS OF LIQUID SOLID SYSTEM (36)

(i) Enhancement of dissolution profile

Dissolution profile of poorly soluble drugs has been enhanced to a greater extent by this liquisolid technique. Liquisolid technique can also employed for Dissolution enhancement of high dose drugs by incorporating some excipients such as HPMC, PEG 35000, which have the tendency to increase the adsorption capacity of carrier and coating material. Khan et al performed the comparative study of liquisolid technique vs solid dispersion techniques on dissolution enhancement of hydrochlorothiazide. This study showed that the dissolution rate of hydrochlorothiazide was increased to 95% when formulated as liquisolid compacts where as the dissolution profile of the same drug was increased to only 88% when formulated as solid dispersion. From the above illustration, it is clear that the liquisolid technique is comparatively more efficient. Three possible

mechanism of enhancement of dissolution by liquisolid compacts includes,(37)

- Enhanced surface area
- Enhanced drug solubility
- Enhanced wettability
- Dissolution profile of Tadalafil was improved by this technique. Studies revealed that dissolution rate of Tadalafil was increased due to crystallinity and reduction in particle size.

(ii) Minimize the variation in drug release due to change in pH.

The solubility of weakly acidic as well as weakly basic drugs is affected mainly by the pH of the local environment and pKa of the compound. Thus pH of GIT has great influence on the dissolution of these weakly acidic or basic drugs. Thus variation in pH also affect the release of the drug. Decrease in drug release due to pH variation can be overcome by formulating these drugs as liquisolid compacts. Hammadi et al formulated loratidine as liquisolid compacts and investigated the influence of pH variation in drug release. The formulated liquisolid compacts of loratidine includes carriers (MCC), liquid vehicle (propylene glycol), and coating material (silica). The liquisolid compacts of loratidine was formulated and dissolution profile was investigated. The study reported that drug release has little influence on pH variation when compared to conventional directly compressible tablets. As a whole, liquid solid compacts was found to be promising technique in minimising the effect of pH variation in drug release. (38)

(iii) Improvement of photo stability of the drug in solid dosage form

Photo-degradation is the potential problem of photo sensitive drugs. Hence photostability study is indispensable for those drugs.(39) Liquid-solid compacts are found to be most useful method in improving the photostability of those photosensitive drugs such as amlodipine. Silicon dioxide which was commonly used in the liquid solid system, possess photo protective activity. This photoprotective activity of the silicon dioxide is responsible for photo protective action of liquisolid compacts, i.e., liquisolid formulations formulated using silicon dioxide as coating material possess high photostability. Khames made a study related to this action of SiO_2. He made several liquisolid formulation of amlodipine, a photosensitive drug using a carrier molecule (Avicel PH 102) and coating material (silicon and titanium dioxide). The formulated liquisolid compacts of amlodipine was irradiated with uv light for about 8 hours. Similarly conventional amlodipine film coated tablets were prepared and irradiated with uv for 8 hours. The study indicated that liquid solid formulation possess effective photoprotective activity when compared to film coated tablets. Some studies show that photoprotective effect was inversely proportional to excipient ratio (R). Thus as a whole, liquisolid compacts serve as a promising method for improving photostability of photosensitive drugs.(40)

(iv) Liq**uisolid compacts as a sustained release tool**

At first, liquisolid compacts was only designed to increase the dissolution profile of poorly aqueous soluble drugs. Later on it is also found to be a promising tool in designing the extended release dosage form. The key advantage of using liquisolid system in designing the extended release dosage form in that they release the drug in zero order kinetics. It also possess some of the limitations, such as high tablet weight, which was due to high dose of the drug. In liquid solid system, sustained release phenomena can be achieved by incorporating hydrophobic carrier in place of hydrophilic carrier. Commonly used hydrophobic carrier in the liquisolid formulation included Eudragit RL and RS, which was mainly responsible for the sustained release action of the liquisolid compacts. SSA value of the hydrophobic

carrier is low compared to that of hydrophilic carrier, which means that large amount of coating material need to be added to make the wet carrier particles, dry and compressible. This will lead to prolong the release of drug. (41)

Prolonged release of the liquisolid compacts can also be achieved by selecting suitable liquid vehicle. Polysorbate 80 plays a critical role in prolonging the release of drug from the formulation. Glass transition temperature of the tween 80 was reduced due to the plasticine effect. As a result, polymeric chain of the tween 80 get coalesced and formed a fine polymeric network with low porosity. This is used to achieve the sustained release phenomena. Javadzadeh et al formulated the sustained release liquisolid compacts of propranolol hydrochloride and further made investigations on it. The results show that the formulated liquisolid compacts release the drug in zero order kinetics. Excipient ratio also affect the release of drug from the liquisolid compacts. Drug release decreases with increases in drug concentration. If liquisolid compacts possess high R value, drug release can be reduced significantly.

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