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(57) Abstract :
This invention is a self-micro emulsifying excipient formulation for enhancing the bioavailability of medicine, which contains an emulsion comprising an oil or other lipid material and a surfactant and a hydrophilic co-surfactant for raising the bioavailability of the drug. It is proposed that at least one medication be emulsified with a self-micro emulsifying excipient, including an oil or other lipid material, a surfactant, and a hydrophilic co-surfactant. The pharmaceuticals created as a result of this approach increase the bioavailability of that drug.

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Diagram:

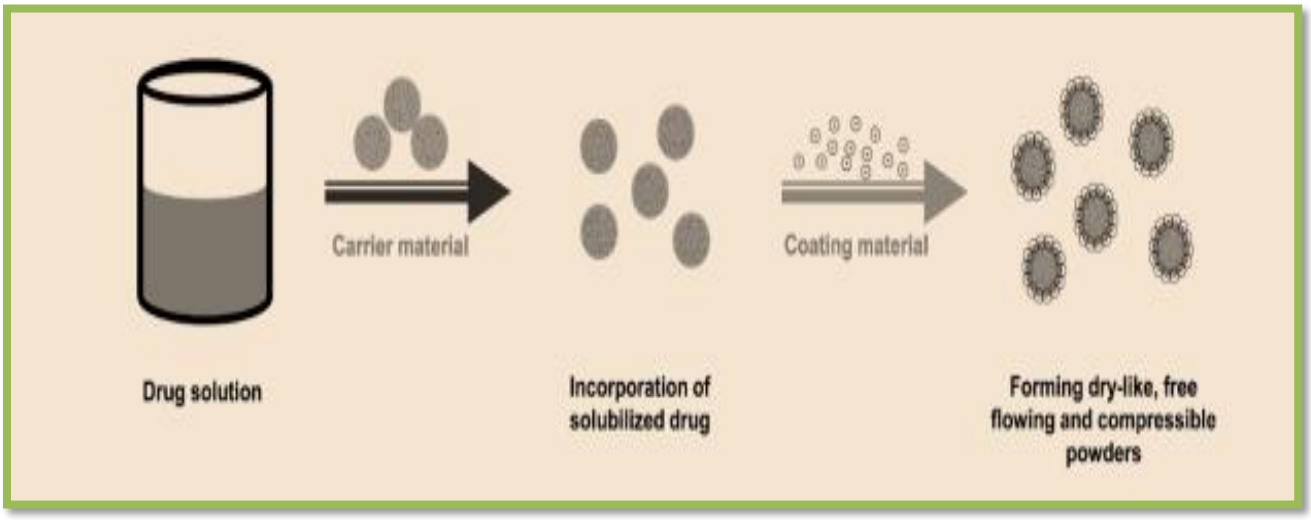

Figure 1: Proposed Invention Process flow

Dated this 13th day of February, 2021

Signature:

FORM 2

THE PATENTS ACT, 1970

(39 of 1970)

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The Patent Rules, 2003

COMPLETE SPECIFICATION

(See section 10 and rule 13)

TITLE OF THE INVENTION

"Self-nanoemulsifying oily formulation process for the poorly water-soluble drugs and method thereof"

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The following specification particularly describes the nature of the invention and the manner in which it is performed:

FIELD OF THE INVENTION

A pharmaceutical excipient is the subject of this invention. A pharmaceutical microemulsion excipient and technique for manufacturing pharmaceutical compositions are the subject of this invention.

BACKGROUND OF THE INVENTION:

In the pharmaceutical industry, it is generally known that there are solid medications that are only marginally soluble in water. Because of their poor solubilities, these medicines have a low degree of bioavailability compared to other medications.

Many previous art procedures have been devised to enhance the solubility and, therefore, the bioavailability of medicines or chemicals that are poorly soluble in the body. The utilization of water-soluble, high-molecular-weight compounds with low melting temperatures, such as Carbowax, in conjunction with an insoluble medicament, is one example of a prior art approach disclosed. However, owing to the low melting point of the compositions produced by this technique, they have poor dispersibility in water. They are consequently unsuitable for use as pharmaceutical excipients in pharmaceutical formulations.

Aside from organic solvents, other techniques of improving the aqueous dissolution rate of poorly water-soluble pharmaceuticals include using poorly water-soluble medications or pharmaceutical compositions that have been solubilized in organic solvents. Among the methods disclosed are those disclosed in the U.S. Pat. No. 4,540,602 to Motoyama and

colleagues, which was issued on September 10, 1985, discloses a process for the preparation of activated pharmaceutical compositions containing a solid drug that is only marginally soluble in water. In this approach, the stages of dissolving or solubilizing a solid medication that is extremely insoluble in water are carried out in a low-boiling-point hydrophobic organic solvent such as lecithin are carried out simultaneously. When the medication has been solubilized, it is next emulsified in the presence of a water-soluble, high-molecular-weight material such as gelatin. The drug is extracted from the emulsion.

A water-soluble matrix such as gelatin or lecithin is used in the technique revealed in the Motoyama et al. reference to solubilize the drug and then resolidify/recrystallize the medication once it has been resolidified. According to the Motoyama et al. procedure, it is necessary to employ organic solvents to solubilize the medication. There are some inherent downsides or drawbacks to using this strategy. Since the drug is solubilized and then recrystallized, the recrystallized product must be reidentified since polymorphic alterations might occur when the drug is recrystallized in a different solvent from the solvent that was used to solubilize it. Furthermore, since the compounds of interest in the Motoyama patent are water-insoluble, organic solvents must be utilized to solubilize the pharmaceuticals of interest to make them soluble. In addition to the health and safety concerns raised by organic solvents, the environmental unfriendliness and safety of organic solvents are also questioned by their usage. Organic solvent recovery and containment devices are extremely expensive. All of these factors associated with their use significantly increase the cost of utilizing organic solvents to increase

the solubility of water-insoluble drugs as organic solvent recovery and containment devices are extremely expensive. The pH of the gastric juices may alter other surface-active excipients known to be harmful to the intestinal mucosa.

Microemulsions have received a great deal of attention in recent years as a possible delivery system for oral drugs. Microemulsions are particularly useful for improving the oral absorption of water-insoluble drugs, such as proteins, by utilizing self-micro emulsifying drug delivery systems (SMEDDS) to increase the solubility of the drug in the upper intestine [Ritschel, 1980]. Self-micro emulsifying drug delivery systems (SMEDDS) are a type of SMEDDS that helps increase the drug's solubility in the upper intestine. Peptide drug delivery methods, in particular, have received a great deal of attention recently. Microemulsions are one such technique.

SARCIAOux et al. (1996) discovered that when a surfactant/cosurfactant blend is applied to a two-phase hydrophilic/lipophilic mixture, it results in a colloidal system that is stable, optically transparent, and isotropic [Sarciaoux et al., 1995].

The ability of microemulsions to spontaneously form (emulsify) at a given temperature, their significant solubilizing properties, their ability to be sterilized by filtration, and their high physical stability have all piqued the interest of researchers interested in using them as oral drug delivery systems [Sarciaoux and colleagues, 1995]. When these mixes are exposed to gastrointestinal fluids, they have the additional property of forming a microemulsion, which is

very desired. Because of their lipophilic or slightly water-soluble nature, SMEDDS are excellent candidates for use as vehicles for the oral administration of lipophilic or slightly water-soluble medicines.

Using SMEDDS technology, Farah et al. [1993, 1993] investigated the possibility of this technique for increasing the in-vitro dissolution of the model medication indomethacin. Farah et al. [1993, 1993] used GELUCIRE as the lipophilic phase, LABRAFAC (saturated C8 -C10 polyglycolide glycerides, HLB=10) as the surfactant, LAUROGLYCOL (propylene glycol laurate, HLB=4), and TRANSCUTOL (diethylene glycol monoethyl ether) as the co-surfactants, and income [1993] discovered that the higher the HLB value of a surfactant and co-surfactant combination, the greater the rate at which an insoluble water medication dissipated. [1993] discovered that When comparing indomethacin in the SMEDDS to indomethacin in the marketed powder form, Farah et al. [1993] found that indomethacin's in vitro dissolution kinetics from the SMEDDS in the gastric medium was significantly enhanced. Although Farah et al. [1993) state that the performance of SMEDDS can be used to increase bioavailability, Farah et al. [1993] do not explain how this is accomplished, nor do they provide any data to support the assertion that increased dissolution rate always corresponds to an increase in bioavailability of the drug. Furthermore, Farah et al. [1993]do not teach or imply that the HLB value of the co-surfactant alone is relevant in increasing the bioavailability of water-insoluble medicines, lipophilic pharmaceuticals, or peptides in the body. According to

Farah et al. [1993,] higher in vitro solubility of indomethacin would result in enhanced bioavailability, which is a pure extrapolation on their part.

Because of this, it would be useful and desirable to have a method of enhancing the solubility and bioavailability of peptides, lipophilic, and weakly water-soluble medicines that avoids the shortcomings of previous art techniques while still achieving the benefits of such methods. Furthermore, it would be desirable to have a method that is entirely aqueous-based to avoid the necessity of recharacterizing pharmaceuticals or drugs by the solubilization method disclosed above and to eliminate the cost and health and environmental safety concerns associated with the use of organic solvents. Increasing the efficiency and effectiveness of medication distribution via the gastrointestinal system would likewise be helpful and desired. A further advantage would be the availability of a self-micro emulsifying excipient formulation in which the bioavailability of poorly water-soluble drugs can be increased by the use of a co-surfactant with a high HLB that can be applied to a drug in an aqueous solution using standard manufacturing and equipment, and that is safe and non-destructive to the intestinal mucosa.

It is possible to take advantage of the potential potency and efficacy of poorly water-soluble drugs or pharmaceutical compositions by combining the method and self-micro emulsifying formulation of the present invention with poorly water-soluble drugs or pharmaceutical compositions to maximize their bioavailability. Specifically, the current invention offers an improved technique and formulation for supplying poorly water-soluble pharmaceuticals with

a manner for increased bioavailability, which encompasses all of the benefits previously discussed.

SUMMARY OF THE PRESENT INVENTION:

By the present invention, a self-micro emulsifying excipient formulation is disclosed for increasing the bioavailability of a drug, which includes an emulsion including an oil or other lipid material, a surfactant, and a hydrophilic co-surfactant. Also, the present invention is a method for making a drug delivery system for increasing the bioavailability of a drug by emulsifying at least one drug with a self-micro emulsifying excipient comprising an oil or other lipid material, a surfactant, and a hydrophilic co-surfactant, and the drugs formulated thereby.

DETAILED DESCRIPTION OF THE INVENTION:

A self-micro emulsifying excipient formulation is revealed for boosting the bioavailability of weakly water-soluble medicines or pharmaceutical compositions by increasing their water solubility. The formulation is typically comprised of an emulsion including an oil or lipid substance, a surfactant, and a hydrophilic co-surfactant, among other ingredients. It is possible to emulsify in the self-micro emulsifying excipient formulation a weakly water-soluble medication or pharmaceutical, enhancing the in vivo bioavailability of the drug or pharmaceutical formulation.

The current invention allows for the treatment of more than one medication or pharmaceutical component and/or formulation to produce the desired pharmaceutical composition according

to the invention. Additional poorly water-soluble medications and/or pharmaceutical components may be treated according to the present invention and utilized in conjunction with other pharmaceuticals and/or pharmaceutical ingredients, whether or not they are poorly water-soluble.

The phrases "drug" and/or "pharmaceutical component" or "formulation" refer to any. A self-micro emulsifying excipient formulation is revealed for boosting the bioavailability of weakly water-soluble medicines or pharmaceutical compositions by increasing their water solubility. The formulation is typically comprised of an emulsion including an oil or lipid substance, a surfactant, and a hydrophilic co-surfactant, among other ingredients. It is possible to emulsify in the self-micro emulsifying excipient formulation a weakly water-soluble medication or pharmaceutical, enhancing the in vivo bioavailability of the drug or pharmaceutical formulation.

The current invention allows for the treatment of more than one medication or pharmaceutical component and/or formulation at a time to produce the desired pharmaceutical composition according to the invention. Additional poorly water-soluble medications and/or pharmaceutical components may be treated according to the present invention and utilized in conjunction with other pharmaceuticals and/or pharmaceutical ingredients, whether or not they are poorly water-soluble.

The phrases "drug" and/or "pharmaceutical component" or "formulation" refer to any pharmaceutical chemical, drug, or composition, including peptides, that is in a solid form, such as powder or granules, and that is intended for oral administration.

Self-micro emulsifying systems emulsify when combined with an aqueous solvent and then form stable microemulsions with diameters in the range of 1 m when exposed to gastrointestinal fluids, as defined by the term.

Oil phase compounds such as GELUCIRE (Gattefosse Corporation, Westwood, N.J.) and other suitable oil phase compounds such as digestible or non-digestible oils and fats such as olive oil, corn oil, soybean oil, cottonseed oil, palm oil, and animal fats can be included in the self-micro emulsifying formulation.

Accordingly, although this invention is described in terms of examples and illustrations, those knowledgeable in the art will appreciate that the invention is not restricted to these visuals and is not meant to depict each component's size. The invention may also not have certain features that are shown in specific drawings for the sake of clarity. These omissions do not affect the various implementations that have been described. However, the pictures and extensive explanations do not restrict the innovation. On the other hand, the scope of the invention as described by the appended claims is intended to embrace all modifications, equivalents, and alternatives. a common phrasing

Instead of implying that something must happen, the term "may" is used as a synonym for "possible" (i.e., meaning must).

Furthermore, "a," "an," and "plurality" all denote "one or more" until explicitly stated differently. This is not to say that the language and phraseology employed herein are restricting in scope, but rather that they are utilized only for descriptive reasons. It is not meant to exclude any other components, additives, integers, or stages when using language like "including," "comprising," "having," "containing," or "involving," as well as variants thereof to imply a wide range of inclusion. Comprising is a synonym for "including," "including," and similar terms in legal contexts. Any mention of document actions and contents is included in this specification to provide a context for the invention. Any or all of these items are not implied or claimed to be part of the previous art or common knowledge in the area relevant to this invention.

The transitional phrase "comprising" is used in this disclosure to denote that the composition, element, or group of elements is also contemplated with the words "consisting of," "consisting of," "selected from the group of consisting of," "including," or "is" following the recitation of the composition, element, or group of elements.

According to the accompanying figures, the present invention is disclosed in different embodiments, wherein the reference numbers used therein correspond to the similar components in the description. Although this invention may be implemented in various ways,

the following description should not be considered limiting. For completeness and clarity, a picture has been included in this disclosure to illustrate the extent of the invention. The following in-depth discussion gives numerical numbers and ranges for various parts of the specified implementations. The figures and ranges shown here are meant to serve as samples only and are not meant to restrict the scope of the claims. Several materials have been identified as appropriate for different implementation aspects. The use of these materials does not limit the breadth of the innovation.

In the present invention, suitable surfactants or emulsifying agents are included in the self-micro emulsifying formulation, which is comprised of LABRAFAC CM 10, a mixture of saturated C8 -C10 poly-glycolysis glycerides (HLB=10, available from Gattefosse Corporation, Westwood, N.J.), as well as other suitable surfactants, such as long alkyl chain sulfonates/sulfates, However, as will be explored in further depth below, the selection of a surfactant seems to be less important than the selection of a co-surfactant.

Preferably hydrophilic, the co-surfactants appropriate for use with the self-emulsifying excipient formulation of the present invention are used in the formulation. According to the HLB system, co-surfactants used in the present invention should have an HLB number larger than 8 based on the HLB system, which is well-known to those knowledgeable in art. The hydrophilic-lipophilic balance (HLB) number is a method of grading surfactants based on the balance between the hydrophilic and lipophilic components of the surfactant or emulsifying agent in question. In other words, the higher the HLB value, the more hydrophilic the surfactant

or emulsifying agent is considered to be. The hydrophilic co-surfactant used in the present invention has a hydrophilic-lipophilic balance (HLB) of higher than 8 in the formulation. Surfactants or emulsifiers in the HLB range of 8-18 are often used to produce oil/water emulsions in most applications. The desired HLB range for the hydrophilic co-surfactant in the current invention is between roughly 10 and 14 in the present invention. The hydrophilic co-surfactants used in the current invention are ideally intermediate-chain length alcohols such as hexanol, pentanol, and octanol, which are known to lower the oil/water contact and enable the spontaneous formation of the emulsion to be achieved. LABRADOR (Gattefosse Corporation, Westwood, N.J.), which is comprised of medium-chain triglycerides derived from coconut oil with an HLB of 14, as well as other hydrophilic co-surfactants with an HLB of greater than 8 such as lauryl alcohol, are preferred hydrophilic co-surfactants for use by the present invention.

The inclusion of an aqueous solvent, such as triacetin, an acetylated derivative of glycerol, such as glyceryl triacetate, or other acceptable solvents may also be included in the self-micro emulsifying formulation for improved performance. Triacetin is an excellent choice since it is miscible in both the oil and lipid phases and may be utilized to solubilize a hydrophobic medication in the oil/lipid phase.

To change the consistency of the emulsion, it is possible to add additional materials and/or chemicals to it. This may be necessary to improve the stability or emolliency of the emulsion. According to Remington's Pharmaceutical Sciences, these components are tragacanth, cetyl alcohol, stearic acid, and/or beeswax, published in 1975.

Creating a drug delivery system for increasing the bioavailability of a drug and/or pharmaceutical ingredient or formulation by emulsifying the drug with a self-micro emulsifying excipient formulation of the present invention includes the steps of solubilizing a poorly water-soluble drug, pharmaceutical ingredient, or formulation thereof in a mixture of surfactant, co-surfactant, and solvent, and emulsifying the drug with the self-micro emulsifying excipient formulation of When the oil phase is ready, it may be added to the solubilized drug formulation and properly mixed. The oil phase can be adequately prepared if heating or other preparation methods are required. After that, the emulsion may be put to an appropriate dosage form, such as soft or hard-filled gelatin capsules, and allowed to cool before being consumed.

According to the present invention, the solubilizing and dissolving capabilities of the self-micro emulsifying formulation may be influenced by the relative amounts of surfactant and co-surfactant included within the formulation. In general, the concentration range of the surfactant/co-surfactant is widely from 15 to 90 percent (v/v), and more ideally varies from around 45 to 55 percent (v/v), depending on the formulation. Generally speaking, the concentration of the co-surfactant varies from 16 to 89 percent (v/v), with a preference for concentrations between 30 and 40 percent (v/v). Generally, the surfactant ratio to cosurfactant in the formulation of the present invention is between 45 and 50 percent (v/v), with the desired range being roughly 25 to 35 percent (v/v). As a rule, the ratio of surfactant to co-surfactant varies between about 1:2 and 1:3, depending on the qualities of the surfactant and/or the co-surfactant in question.

The active drug or pharmaceutical ingredient that is lipophilic and poorly water-soluble by the present invention can include, for example, nifedipine, griseofulvin, cyclosporin, digoxin, itraconazole, carbamazepine, piroxicam, fluconazole, indomethacin, steroids, ibuprofen, diazepam, finasteride, and diflunisal. In line with the present invention, additional pharmaceutical substances or other lipophilic medications or weakly water-soluble medications may also be employed in combination with the current invention. This list is not intended to be comprehensive; rather, it is intended to offer examples of appropriate compounds that may be employed in line with the principles of the present invention.

Dissolution/bioavailability investigations have been carried out by the applicant, which has shown an enhanced dissolution rate of water-insoluble pharmaceutical components and pharmaceuticals by the present invention. In particular, as described in greater detail below, the applicant has demonstrated an improvement in the bioavailability of the poorly water-soluble drug nifedipine by using either a co-surfactant with a high HLB (HLB=14) value or a co-surfactant with a low HLB (HLB=4) value, even though both formulations appeared to solubilize the drug in an equal amount. The area under the plasma-time curve (AUC) for the formulation including a high HLB co-surfactant was five times bigger than that for the drug alone (powder) and two times greater than that for the formulation containing a low HLB co-surfactant, respectively. It was concluded from this study that the HLB value of the co-surfactant plays an important role in increasing the bioavailability of lipophilic or poorly water-

soluble drugs, possibly by facilitating the solubilization of poorly water-soluble drugs, increasing the permeation of the drug across the intestinal wall, or a combination of the two.

For water-insoluble medications, theoretical considerations of drug dissolution and absorption in the human gastrointestinal system imply that two independent factors will affect drug absorption: the dissolution rate, the amount of dissolution, and the dosage of drug administered. A significant finding of this study is that, for water-insoluble medications, the percentage dosage of medication absorbed is inversely related to dose and directly proportional to the rate at which the drug is dissolved. As a result, solubilization and dissolution in vivo are major factors of medication absorption in clinical settings. In the drawing section, figure 1 discloses the proposed concept flow diagram.

We Claim:

1. For increasing the bioavailability of a drug, a self-micro emulsifying excipient formulation comprising: an emulsion consisting primarily of an oil or other oil-like material, a surfactant, and a hydrophilic co-surfactant, with the hydrophilic co-surfactant having a hydrophilic-lipophilic balance (HLB) greater than 8.
2. Method of manufacturing a drug delivery system for increasing the bioavailability of a drug by emulsifying at least one drug with a self-emulsifying excipient comprising an oil or other lipid material, a surfactant, a hydrophilic co-surfactant, and a solvent that includes triacetin for increasing the bioavailability of a drug is disclosed.
3. A self-micro emulsifying excipient formulation according to claim 1, wherein said hydrophilic co-surfactant has a hydrophilic-lipophilic balance (HLB) between approximately 10 and 14 and said hydrophilic co-surfactant has a hydrophilic-lipophilic balance (HLB) between approximately 10 and 14.
4. A self-micro emulsifying excipient formulation, as defined in claim 1, in which the hydrophilic co-surfactant is alcohol, is used as the hydrophilic co-surfactant.
5. A solvent is included in the self-micro emulsifying excipient formulation described in claim 1 in addition to the excipient.

Dated this 13th day of February, 2022

Signature: 

Applicant(s)

Dr.P. Jacquline Rosy et. al.

ABSTRACT

Self-nanoemulsifying oily formulation process for the poorly water-soluble drugs and method thereof

This invention is a self-micro emulsifying excipient formulation for enhancing the bioavailability of medicine, which contains an emulsion comprising an oil or other lipid material and a surfactant and a hydrophilic co-surfactant for raising the bioavailability of the drug. It is proposed that at least one medication be emulsified with a self-micro emulsifying excipient, including an oil or other lipid material, a surfactant, and a hydrophilic co-surfactant. The pharmaceuticals created as a result of this approach increase the bioavailability of that drug.

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