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(54) CONTROLLED RELEASE DOSAGE FORMS

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(57) **ABSTRACT**

The invention provides stable controlled release monolithic coating compositions for use in coating pharmaceutical oral dosage forms comprising a polyglycol having a melting point greater than 55° C. and an aqueous dispersion of a neutral ester copolymer lacking functional groups.

CONTROLLED RELEASE DOSAGE FORMS

RELATED APPLICATIONS

[0001] This application claims priority from U.S. provisional patent application No. 60/357,851 filed Feb. 21, 2002.

FIELD OF THE INVENTION

[0002] This invention relates to a novel monolithic film coating for obtaining controlled release of drugs from oral dosage forms.

BACKGROUND

[0003] The manner in which chemicals or drugs are administered has gained increasing attention in the past two decades. Normally, a chemical is administered in a high dose at a given time only to have to repeat that dose several hours or days later. This is not economical and sometimes results in damaging side effects. As a consequence, increasing attention has been focused on methods of giving drugs continually for prolonged time periods and in a controlled fashion. Controlled or sustained release dosage forms provide a therapeutic dose of the drug soon after administration, and then gradually release the drug over an extended period of time. The primary method of accomplishing this controlled release has been through incorporating the drugs within polymers or to surround or encapsulate a core comprising the drug with a polymer coat. Depending on the type and amount of drug, as well as the type and amount of polymer and other pharmaceutically acceptable excipients the desired controlled release profile can be obtained.

[0004] The majority of polymers used to develop coatings for controlled release dosage forms are hydrophobic and can be applied either dry, from a solution, or suspension. As most of these polymers are poorly soluble in water, they are usually applied by dissolving the polymer in an organic solvent and then sprayed onto the drug core and evaporating off the solvent. The use of organic solvents, however, is considered problematic for several reasons. The most obvious reason relates to the safety hazards associated with the use of organic solvents. Organic solvents in general are highly flammable and carcinogenic. Further, organic solvents are expensive and the storage, disposal and use of organic solvents raise environmental concerns. Accordingly, it would be desirable to prepare aqueous suspensions or solutions of controlled release coatings comprising hydrophobic polymers suitable for coating a wide variety of drug cores.

[0005] Eudragit® NE30D, which contains 30% solids, is one of the first aqueous polymeric dispersions used for coating pharmaceutical dosage forms. Eudragit® NE30D has many advantages over other polymers for use as a film former for obtaining a controlled release drug profile and is thus ideally suited for controlled or sustained release drug formulations. The polymer forms a soft, flexible film at room temperature without any plasticizer. Also, no reactions or absorptive effects are observed when the polymer comes in direct contact with a therapeutically active agent. It is prepared by emulsion polymerization and consists of neutral copolymers of ethyl acrylate-methyl methacylate esters that are insoluble over the entire physiological pH range but will still swell in water and give permeable membranes. The permeability is independent of pH and is thus suitable for the development of pH-independent modified-release oral dosage forms, provided that the solubility of the drug is also pH-independent.

[0006] One of the most significant differences between aqueous polymeric solutions and dispersions is the role water plays during film formation. In solutions, water is a solvent and drying is accompanied by an excessive increase in viscosity, which in turn suppresses the rate of evaporation. Excess energy is therefore required to drive off the water. In contrast, in polymeric dispersions such as Eudragit® NE30D, water is only a dispersion medium and does not solvate the polymers. Consequently, less heat is needed to evaporate the water. Fast water evaporation coupled with the high solids content of the dispersion significantly reduces processing time. These properties are especially critical when dealing with highly water-soluble or moisture sensitive therapeutically active agents.

[0007] The pigment binding capacity of Eudragit® NE30D is very high, so that up to ~2-3 parts by weight of additives can be incorporated into 1 part by weight of dry polymer without affecting the film properties. The polymer is also compatible with a wide variety of pharmaceutical excipients.

[0008] Plasticizers are generally added to coating formulations to modify the physical properties i.e., the glass transition temperature (Tg) of the polymer to make it more usable. The Tg is the temperature at which an amorphous polymer (or the amorphous regions in a partially crystalline polymer) changes from a hard and relatively brittle condition to a viscous or rubbery condition. Plasticizers function by decreasing the Tg of the polymer so that under ambient conditions the films are softer, more pliable and often stronger, and thus better able to resist mechanical stress. Eudragit® NE30D, however, has a low Tg and accordingly does not require the use of plasticizers. In fact, addition of plasticizers can be detrimental as it can increase the viscosity of the Eudragit® NE30D formulation and negate one of the distinct advantages of the dispersion over the polymeric solution. Incorporation of plasticizers into Eudragit® NE30D formulations can also increase the tackiness of the coat and complicate the coating process (Ghebre-Sellassie and Nesbit. *Application of Eudragit E30D in Controlled-Release Coatings* in Aqueous Polymeric Coatings for Pharmaceutical Forms, J. McGinity Ed., 1989, Marcel Dekker, Inc., pp 247-266).

[0009] Due to its low Tg, Eudragit® NE30D is sensitive to excessive drying conditions or exposure to high temperatures. Ghebre-Sellassie and Nesbit (*Application of Eudragit E30D in Controlled-Release Coatings* in Aqueous Polymeric Coatings for Pharmaceutical Forms, J. McGinity Ed., 1989, Marcel Dekker, Inc., pp 247-266) state that excessive drying of Eudragit® NE30D coats can be detrimental as such conditions do not allow the coating formulation to spread out evenly and promote particle deformation and coalescence. Also, during the coating process, the product temperature should be kept at around 26° C. If the product temperature is very high, the coating material becomes tacky owing to the low Tg of Eudragit® NE30D, which leads to agglomeration of the coated product. Ghebre-Sellassie and Nesbit also emphasize that Eudragit® NE30D coated products should not be stored at temperatures above 40° C., as stability tests conducted at elevated temperatures may not

correlate with the long-term behavior of Eudragit® NE30D coated products at room temperature.

[0010] Attempts have been made in the prior art to design microporous aqueous polymer coatings suitable for use on drug cores to obtain controlled or sustained release profiles using the Eudragits, and in particular Eudragit® NE30D. U.S. Pat. No. 5,529,791 for example, teaches controlled release dosage forms of Diltiazem in which the Diltiazem drug core is surrounded by a water-soluble and/or dispersible film forming polymer or copolymer constituting the microporous membrane. The polymers or copolymers taught include the polyacrylates and polymethacrylates of the Eudragit type, such as Eudragit NE30D, L30D, and RS30 D, ethylcelluloses, hydroxypropyl cellulose and hydroxypropylmethylcellulose and their derivatives. In addition to the polymer or copolymer, the microporous membrane contains, preferably, talc and/or magnesium stearate as a lubricant, polyvinylpyrrolidone as a plasticizer, titanium dioxide as a pigment, Tween 80 as an emulsifier, and silicone oil as an antifoaming agent. Other plasticizers taught include triacetin, dibutylpthalate, dibutylsebacate, citric acid esters, polyethyleneglycols, and polypropyleneglycols. The Eudragit® NE30D coated beads were cured for 16 hours at 50° C. (Example 3) or for 15 hours at 45° C., 5-10° C. beyond the recommended temperature for Eudragit® NE30D. Further, long-term stabilization data was not presented for the coated products, and accordingly, it is not known what effect the elevated temperature had, if any, on the stability of the controlled release dosage form of Diltiazem.

[0011] U.S. Pat. No. 5,286,493 is directed to stabilized controlled release formulations having an aqueous acrylic polymer coating. The '493 patent also teaches the use of controlled release coatings covering a solid dosage form. The coating is derived from aqueous dispersions of an acrylic resin, which provides a substantially stable release pattern of a drug from the dosage form. The acrylic resins taught are the ammonio methacrylate co-polymers as for example Eudragit® RL30D, RS30D and combinations thereof. The acrylic coatings include an effective amount of a suitable plasticizing agent. The stable Eudragit® RL30D and/or RS30D coated products are cured at temperatures above the Tg of the acrylic polymers. The '493 patent does not teach the use of Eudragit® NE30D.

[0012] U.S. Pat. No. 5,478,573 teaches delayed, sustained-release propranolol pharmaceutical preparations purportedly achieved by surrounding a water-soluble drug core with a hydratable diffusion barrier which delays drug release by for about 2-10 hours. The hydratable diffusion barrier is said to comprise a film-forming polymer such as acrylic resin or ethyl cellulose or mixtures thereof and an additive which con trolls the rate of hydration and permeability of the diffusion barrier. The preferred insoluble film-forming polymers are aqueous dispersions of fully esterified acrylic resins such as Eudragit® NE30D. The additives controlling the rate of hydration and permeability of the diffusion barrier are preferably selected from the group consisting of fully esterified acryclic resins containing quaternary amine side chains, anionic surfactants, lubricants, plasticizers, inert water soluble materials and mixtures thereof. The '573 patent teaches that the drug beads coated with the aqueous polymeric dispersion are dried at 35° C. to 60° C. for 8 hours to 5 days. No data is presented on the long-term stability of the products.

[0013] Another controlled release pharmaceutical dosage form using an aqueous acrylic polymer dispersion is taught in U.S. Pat. No. 5,871,776. The controlled release profile is obtained, however, using multiple layers of films. The outermost layer is comprised of the aqueous acrylic polymer dispersion. The preferred acrylic polymer is Eudragit® NE30D. The coatings may also contain other pharmaceutically acceptable excipients such as fillers, anti-adherents, pharmaceutically acceptable pigments and lubricants/glidants. The coated drug pellets are cured at a temperature in the range of from about 30° C. to about 50° C., preferably from about 35° C. to about 45° C. and most preferably about 40° C. for a period of about 5 to about 10 days, an preferably about 7 days. The inventors surprisingly found that in contrast to the preferred short curing times taught in the prior art, long curing times help stabilize the release of the drug from the coated pellets after long storage periods.

[0014] International Patent Publication No. WO 02/058677 describes a film coating composition comprising an aqueous acrylic polymer dispersion, a surfactant, and sodium stearyl fumarate. The acrylic polymer dispersion is preferably Eudragit® NE30D. There does not appear to be any teaching as to the curing temperature and furthermore no data is presented with regard to long-term stability of the coated product.

[0015] In summary, it would seem that although the prior art teaches the use of aqueous acrylic dispersion coatings of Eudragit® NE30D, in most part, the prior art does not seem to have overcome long term stability problems of products coated with aqueous Eudragit® NE30D dispersions. Where the products have been found to be stable, the length of curing is very long and this is inefficient to the manufacturing process and also raises problems with storage of scale-up product. Accordingly, and given the advantages and versatility of Eudragit® NE30D, it would desirable that a stable controlled or sustained release coat be developed with short curing times to enhance process times. It is therefore an object of this invention to develop such a product.

SUMMARY OF THE INVENTION

[0016] This invention is related to a novel monolithic stable controlled release coating for use in coating oral pharmaceutical dosage forms.

[0017] In one aspect, the coating comprises an aqueous dispersion of a neutral ester copolymer without any functional groups; a poly glycol having a melting point greater than 55° C., and one or more pharmaceutically acceptable excipients; wherein said coating composition is coated onto said oral pharmaceutical dosage forms and cured at a temperature at least equal to or greater than the melting point of the poly glycol.

[0018] In another aspect, the invention provides a controlled release dosage form comprising a core, wherein the core comprises an effective amount of at least one therapeutically active agent, and one or more first pharmaceutically acceptable excipients, and a stable controlled release monolithic coating composition for coating said core, said coating comprising an aqueous dispersion of a neutral ester copolymer without any functional groups; a poly glycol having a melting point greater than 55° C., and one or more pharmaceutically acceptable excipients; wherein said coating composition is coated onto said oral pharmaceutical

dosage forms and cured at a temperature at least equal to or greater than the melting point of the poly glycol.

[0019] In one embodiment, the neutral ester copolymer without any functional groups is selected from the group consisting of Eudragit® NE30D and Eudragit® NE40D. Preferably, the neutral ester copolymer without any functional groups is Eudragit® NE30D. The neutral ester copolymer without any functional groups is present in an amount from about 1% to about 35% by weight of the coating composition.

[0020] In one embodiment, the poly glycol is selected from the group consisting of polyethylene glycol 6000, polyethylene glycol 8000, polyethylene glycol 10000 and polyethylene glycol 20000. The poly glycol is present in an amount from about 0.1% to about 10% by weight of the coat composition. Preferably, the poly glycol is polyethylene glycol 8000.

[0021] The addition of pharmaceutically acceptable excipients to the coating composition is contemplated and can include anti-tacking agents, emulsifying agents, hydrophilic agents, anti-foaming agents, flavourants, colorants, sweeteners and any combination thereof. The preferred ant-tacking agent is talc, the preferred hydrophilic agent is hydroxypropyl methylcellulose, the preferred ant-foaming agent is simethicone, the preferred emulsifying agent is polyoxyethylene sorbitan mono-oleate, and the preferred colorant is titanium dioxide.

DETAILED DESCRIPTION OF THE INVENTION

[0022] The present invention is directed to novel aqueous dispersions of neutral ester copolymers without any functional groups suitable for use as coatings for controlled or sustained release drug dosage forms. The coating formulation is quite versatile in that it can be used to coat a variety of drug cores and can be easily manipulated to obtain the desired drug release profile. In another embodiment, the invention consists of a controlled release pharmaceutical composition, in one embodiment, a tablet, comprising at least one form of a therapeutically active agent, wherein the pharmaceutical composition comprises a core and a stable controlled release coating of the invention.

[0023] I. Cores

[0024] The core comprises an effective amount of a therapeutically active agent and at least one pharmaceutically acceptable excipient, in one embodiment a lubricant, a binder and/or filler, and optionally a glidants as well as other pharmaceutically acceptable excipients.

[0025] A wide variety of therapeutically active agents is contemplated. These include but are not limited to anti-tussives, anti-histamines, decongestants, alkaloids, mineral supplements, vitamins, antacids, ion exchange resins, anti-cholesterolemics, anti-lipid agents, anti-arrhythmics, anti-pyretics, analgesics, appetite suppressants, anti-depressants, expectorants, anti-anxiety agents, anti-ulcer agents, anti-inflammatory substances, coronary dilators, opioid agonists, cerebral dilators, peripheral vasodilators, antibiotics, anti-virals, psycho-tropics, anti-manics, stimulants, gastrointestinal agents, sedatives, anti-diarrheal agents, anti-anginal drugs, vasodilators, anti-hypertensive drugs, vasoconstrictors, migraine treatments, anti-infectives, tranquilizers, anti-psychotics, anti-tumor drugs, anticoagulants, antithrombic drugs, hypnotics, anti-emetics, anti-nauseants, anti-convulsants, neuromuscular drugs, hyper- and hypoglycemic agents, thyroid and anti-thyroid agents, diuretics, anti-spasmodics, uterine relaxants, mineral and nutritionaql additives, anti-obesity drugs, anabolic drugs, erythropoietic drugs, anti-asthmatics, cough suppressants, mucolytics, H_2-antagonists, anti-uricemic drugs. Mixtures are operable depending on the type of drugs. The skilled artisan will know, based on his technical knowledge, which drug combinations are acceptable. The therapeutically active agent(s) are present in an amount from about 5% to about 99% by weight of the cores. The amount present is highly dependent on the agent(s), the desired controlled release profile, and the strength of the desired dosage form. Different forms of the therapeutically active agent are also contemplated. One form of the therapeutically active agent may be the individually optically active enantiomers of the therapeutically active agent. Pharmaceutically acceptable salts, as for example pharmaceutically acceptable addition salts, of the therapeutically active agent(s) are also suitable. Suitable pharmaceutically acceptable addition salts may be the hydrochloride salt, the hydrobromide salt, the hydroiodide salt, the saccharinate salt etc.

[0026] Glidants improve the flowabilitye of the excipient powder by reducing intraparticulate friction. This is especially important during tablet production at high production speeds and during direct compaction. Examples of glidants include but are not limited to starch, talc, lactose, stearates (such as for example magnesium stearate), dibasic calcium phosphate, magnesium carbonate, magnesium oxide, calcium silicate, Cabosil™, colloidal silica (Syloid™) and silicon dioxide aerogels. Glidants, if present, range in amounts from greater than about 0% to about 20%, with amounts of about 0.1% to about 5% being typical.

[0027] Lubricants ensure that tablet formation and ejection can occur with low friction between the solid and the die wall. High friction during tabletting can cause a series of problems, including inadequate tablet quality (capping or even fragmentation of tablets during ejection, and vertical scratches on tablet edges) and may even stop production. Lubricants are thus included in almost all tablet formulations. Such lubricants include but are not limited to adipic acid, magnesium stearate, calcium stearate, zinc stearate, hydrogenated vegetable oils, sodium chloride, sterotex, polyoxyethylene, glyceryl monostearate, talc, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, magnesium lauryl sulfate, sodium stearyl fumarate, light mineral oil and the like may be employed, with sodium stearyl fumarate being preferred. Waxy fatty acid esters, such as glyceryl behenate, sold as "Compritol™" products, can be used. Other useful commercial lubricants include "Stear-O-Wet™" and "Myvatex™ TL". Mixtures are operable. Lubricants are used in amounts typically ranging from greater than about 0% to about 10%, with about 0.01% to about 5.0% by weight of the tablet preferred.

[0028] It is well known in the art that besides reducing friction, lubricants may cause undesirable changes in the properties of a tablet. The presence of a lubricant in the excipient powder is thought to interfere in a deleterious way with the bonding between the particles during compaction and thus reduce tablet strength. Because many lubricants are hydrophobic, tablet disintegration and dissolution are often

retarded by the addition of a lubricant. Such negative effects are strongly related to the amount of lubricant present. Other considerations known in the art include the manner in which a lubricant is mixed, the total mixing time and the mixing intensity. In order to avoid these negative effects, hydrophilic substances may be substituted for the hydrophobic lubricants. Examples include, but are not limited to, surface-active agents and polyethylene glycol. A combination of hydrophilic and hydrophobic substances can also be used.

[0029] Anti-adherents reduce adhesion between the excipient powder mixture and the punch faces and thus prevent particles sticking to the punches, a phenomenon know in the art as "sticking" or "picking", and is affected by the moisture content of the powder. One example of anti-adherent is microcrystalline cellulose. Many lubricants such as magnesium stearate have also antiadherent properties. However, other substances with limited ability to reduce friction can also act as antiadherents. Such substances include for example talc and starch. Mixtures are operable. Antiadherents, if present, range from about 0% to about 20% by weight of the tablet depending on the antiadherent being used.

[0030] Sorbents are substances that are capable of sorbing some quantities of fluids in an apparently dry state. Thus, oils or oil-drug solutions can be incorporated into a powder mixture, which is granulated and compacted into tablets. Other examples of sorbing substances include microcrystalline cellulose and silica.

[0031] Diluents or fillers are added to increase the bulk weight of the blend resulting in a practical size for compression. The ideal diluent or filler should fulfill a series of requirements, such as: be chemically inert, be non-hygroscopic, be biocompatible, possess good biopharmaceutical properties (e.g. water soluble or hydrophilic), good technical properties (such as compactibility and dilution capacity), have an acceptable taste and be cheap. As a single substance cannot fulfill all these requirements, different substances have gained use as diluents or fillers in tablets.

[0032] Lactose is a common filler in tablets. It possesses a series of good filler properties, e.g. dissolves readily in water, has a pleasant taste, is non-hygroscopic and fairly non-reactive and shows good compactibility. Other sugars or sugar alcohols, such as glucose, sucrose, sorbitol and mannitol, have been used as alternative fillers to lactose, primarily in lozenges or chewable tablets because of their pleasant taste. Mannitol has a negative heat of solution and imparts a cooling sensation when sucked or chewed.

[0033] Apart from sugars, perhaps the most widely used fillers are celluloses in powder forms of different types. Celluloses are biocompatible, chemically inert, and have good tablet forming and disintegrating properties. They are therefore used also as dry binders and disintegrants in tablets. They are compatible with many drugs but, owing to their hygroscopicity, may be incompatible with drugs prone to hydrolyse in the solid state. The most common type of cellulose powder used in tablet formulation is microcrystalline cellulose.

[0034] Another important example of a diluent or filler is dibasic and tribasic calcium phosphate, which is insoluble in water and non-hygroscopic but is hydrophilic, i.e. easily wetted by water. Other examples of diluents include but are not limited to di- and tri-basic starch, calcium carbonate, calcium sulfate, and modified starches. Many diluents are marketed in "direct compression" form, which adds other desirable properties, such as flow and binding. There are no typical ranges used for the diluents, as targeted dose and size of a tablet are variables that influence the amount of diluent that should be used.

[0035] Binders (also sometimes called adhesives) are added to ensure that tablets can be formed with the required mechanical strength. Binders can be added in different ways: (1) As a dry powder, which is mixed with other ingredients before wet agglomeration; (2) As a solution, which is used as agglomeration liquid during wet agglomeration. Such binders are often referred to as "solution binders", and (3) As a dry powder, which is mixed with the other ingredients before compaction (slugging or tabletting). Such binders are often referred to as "dry binders". Common traditional solution binders are starch, sucrose, and gelatin. More commonly used binders with improved adhesive properties, are polymers such as polyvinylpyrrolidone and cellulose derivates such as for example hydropropyl methylcellulose. Examples of dry binders include microcrystalline cellulose and crosslinked polyvinylpyrrolidone. Other examples of binders include but are not limited to pregelatinized starches, methylcellulose, sodium carboxymethylcellulose, ethylcellulose, polyacrylamides, polyvinyloxoazolidone and polyvinylalcohols. Binders, if present, range in amounts from about greater than about 0% to about 25% depending on the binder used.

[0036] The manufacturing process of the core can be as follows. The at least one therapeutically active agent is first granulated with the at least one binder, in one embodiment a granulator, but not necessarily a fluidized bed granulator. The at least one binder is first dissolved or dispersed in a suitable solvent, in one embodiment water. The solution or suspension of the at least one binder is then sprayed onto the at least one therapeutically active agent in a granulator, in one embodiment a fluidized bed granulator. For example, fluidized bed granulators manufactured by Glatt (Germany) or Aeromatic (Switzerland) can be used for this operation. An alternative process can be to use a conventional or high shear mixer for granulation. If necessary, the at least one therapeutically active agent can be mixed with a filler, prior to the granulation step. Granules once dried can be mixed with the other pharmaceutically acceptable excipients, especially with the at least one lubricant, but also with at least one glidant and any other pharmaceutically acceptable excipient suitable to improve processing. The mixture of granules (in one embodiment with the at least one lubricant), and optionally at least one glidant is pressed into tablets. Alternatively, the at least one therapeutically active agent and the at least one lubricant can be mixed in a granulator, in one embodiment a fluidized bed granulator, and heated to the melting point of the at least one lubricant to form granules. This mixture can then be mixed with at least one suitable filler and compressed into tablets. Also, it is possible to mix the at least one therapeutically active agent and the at least one lubricant (in one embodiment polyvinyl alcohol) in a granulator, in one embodiment a fluidized bed granulator, and then to press the resulting granules into tablets. Tablets can be obtained by standard techniques, in one embodiment on a (rotary) press (for example Manesty Betapress®) fitted with suitable punches. The resulting tablets are hereinafter referred as tablet cores.

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