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(54) **ONCE-A-DAY OXYCODONE FORMULATIONS**

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(57) **ABSTRACT**

The invention is directed to sustained release formulations containing oxycodone or a pharmaceutically acceptable salt thereof which provide a mean C_{24}/C_{max} oxycodone ratio of 0.6 to 1.0 or 0.7 to 1 after oral administration at steady state to patients and methods thereof.

ONCE-A-DAY OXYCODONE FORMULATIONS

[0001] This application claims benefit of U.S. Provisional Application No. 60/288,211, filed May 2, 2001, the disclosure of which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The invention is directed to sustained release formulations containing oxycodone or a pharmaceutically acceptable salt thereof which is suitable for administration to a patient.

BACKGROUND OF THE INVENTION

[0003] Once-a-day sustained release opioid formulations are disclosed in U.S. Pat. Nos. 5,478,577; 5,672,360; 5,958,459; 6,103,261; 6,143,332; 5,965,161; 5,958,452 and 5,968,551. All documents cited herein, including the foregoing, are incorporated by reference in their entireties for all purposes.

SUMMARY AND OBJECTS OF THE INVENTION

[0004] It is an object of the present invention to provide an oxycodone formulation suitable for once daily administration for effective pain management.

[0005] It is an object of preferred embodiments of the present invention to provide a pharmaceutically acceptable dosage form for orally administering oxycodone to provide analgesic therapy beyond its relatively short half-life over an extended period of time, and having a duration of pain relief of at least 24-hours.

[0006] The above objects and others are attained by the present invention, which is directed to a dosage form comprising an analgesically effective amount of oxycodone or a pharmaceutically acceptable salt thereof and a sustained release material, the dosage form providing an analgesic effect for at least about 24 hours after oral administration at steady state to human patients; and the dosage form providing a mean C_{24}/C_{max} oxycodone ratio of 0.6 to 1.0 after oral administration at steady state to the patients.

[0007] In certain embodiments of the invention, the dosage form after administration to patients provides a mean T_{max} of oxycodone in-vivo which occurs at about 2 to about 17 hours (e.g., about 2 to about 8 hours) after administration at steady state of the dosage form.

[0008] In certain embodiments of the invention, the mean T_{max} of oxycodone in-vivo occurs at about 6.5 hours to about 17 hours, at about 8 to about 16 hours, at about 10 to about 16 hours, or at about 12 to about 16 hours after administration at steady state of the dosage form.

[0009] In certain embodiments of the invention, the dosage form provides an analgesic effect for at least about 24 hours after administration of the dosage form to human patients at steady state; and provides a mean C_{24}/C_{max} oxycodone ratio of 0.60 to 1.0 after administration at steady state to patients.

[0010] In certain embodiments of the invention, the dosage form provides an analgesic effect for at least about 24 hours after administration at steady state to human patients; and provides a mean C_{24}/C_{max} oxycodone ratio of 0.60 to 1.0 or 0.7 to 1.0 after administration at steady state to patients. In certain embodiments of the invention, the dosage form provides an in-vitro release rate, of oxycodone or a pharmaceutically acceptable salt thereof, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH of between 1.6 and 7.2 at 37° C. of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80% at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hours, and greater than about 50% at 24 hours.

[0011] In certain preferred embodiments the sustained release oral dosage form of the present invention provides oxycodone plasma levels which are effective for 24 hourly dosing, characterized by a W_{50} for the oxycodone of between 4 and 24 hours after administration at steady state. In certain embodiments, the W_{50} is at least 4 hours, preferably at least 12 hours, and more preferably at least 18 hours, after administration at steady state.

[0012] In certain embodiments the sustained release oral dosage form of the present invention comprises a matrix which includes a sustained release material and oxycodone or a pharmaceutically acceptable salt thereof. In certain embodiments, the matrix is compressed into a tablet and may be optionally overcoated with a coating that in addition to the sustained release material of the matrix may control the release of the oxycodone or pharmaceutically acceptable salt thereof from the formulation, such that blood levels of active ingredient are maintained within the therapeutic range over an extended period of time. In certain alternate embodiments, the matrix is encapsulated.

[0013] In certain embodiments, the sustained release oral dosage form of the present invention comprises a plurality of pharmaceutically acceptable sustained release matrices comprising oxycodone or a pharmaceutically acceptable salt thereof, the dosage form maintaining the blood plasma levels of oxycodone within the therapeutic range over an extended period of time when administered to patients.

[0014] Preferably, the formulations prepared in accordance with the present invention can be presented in tablet, capsule, or in any other suitable unit dosage form.

[0015] In certain embodiments the sustained release oral dosage form of the present invention is an osmotic dosage form which comprises a single layer or bilayer core comprising oxycodone or a pharmaceutically acceptable salt thereof; an expandable polymer; a semipermeable membrane surrounding the core; and a passageway disposed in the semipermeable membrane for sustained release of the oxycodone or pharmaceutically acceptable salt thereof, such that blood levels of active ingredient are maintained within the therapeutic range over an extended period of time when administered to patients.

[0016] In certain embodiments the sustained release oral dosage form of the present invention comprises a substantially homogenous core comprising oxycodone or a pharmaceutically acceptable salt thereof and an expandable polymer; a semipermeable membrane surrounding the core; and a passageway disposed in the semipermeable membrane for sustained release of the oxycodone or pharmaceutically acceptable salt thereof, such that blood levels of active ingredient are maintained within the therapeutic range over an extended period of time when administered to a patients.

[0017] In certain embodiments of the present invention, there is provided a method of treating pain associated

conditions in patients requiring such treatment which method includes administering to a patient an effective amount of oxycodone or a pharmaceutically acceptable salt thereof in a sustained release dosage form as described herein.

[0018] In certain embodiments, the invention is directed to the use of a sustained release dosage form comprising a pharmaceutically acceptable matrix comprising oxycodone or a pharmaceutically acceptable salt thereof and a sustained release material in the production of an analgesic preparation for oral administration to human patients on a once a day basis, to provide an analgesic effect for at least about 24 hours and a mean C_{24}/C_{max} oxycodone ratio of 0.6 to 1.0 after administration at steady state to said patients.

[0019] In certain embodiments, the invention is directed to the use of a sustained release oral dosage form comprising a bilayer core comprising a drug layer comprising an analgesically effective amount of oxycodone or a pharmaceutically acceptable salt thereof; and a displacement layer comprising an osmopolymer; and a semipermeable wall surrounding the bilayer core having a passageway disposed therein for the release of said oxycodone or pharmaceutically acceptable salt thereof; in the production of an analgesic preparation for oral administration to human patients to provide an analgesic effect at least about 24 hours after oral administration at steady state to human patients; and to provide a mean C_{24}/C_{max} oxycodone ratio of 0.6 to 1.0 after administration at steady state to said patients.

[0020] In certain embodiments, the invention is directed to the use of a sustained release dosage form comprising a plurality of sustained release matrices comprising oxycodone or a pharmaceutically acceptable salt thereof and a sustained release material, in the production of an analgesic preparation for oral administration to a patient on a once-a-day basis, to provide an analgesic effect for at least 24 hours after oral administration at steady state to human patients; and to provide a mean C_{24}/C_{max} oxycodone ration of 0.6 to 1.0 after oral administration at steady state to said patients.

[0021] The term "C_{max}" as it is used herein is the highest plasma concentration of the drug attained within the dosing interval.

[0022] The term "C_{24}" as it is used herein is the plasma concentration of the drug at 24 hours after administration.

[0023] The term "T_{max}" as it is used herein is the time period which elapses after administration of the dosage form until the plasma concentration of the drug attains the highest plasma concentration within the dosing interval.

[0024] The term "W_{50}" for purposes of the present invention is the duration over which the plasma concentrations are equal to or greater than 50% of the peak concentration. The parameter is determined by linear interpolation of the observed data and represents the difference in time between the first (or only) upslope crossing and the last (or only) downslope crossing in the plasma profile.

[0025] The term "C_{24}/C_{max} ratio" is defined for purposes of the present invention as the ratio of the plasma concentration of the drug at 24 hours after administration to the highest plasma concentration of the drug attained within the dosing interval.

[0026] The term "USP Basket Method" is the Basket Method described in U.S. Pharmacopoeia XXII (1990), herein incorporated by reference.

[0027] The term "steady state" means that the amount of the drug reaching the system is approximately the same as the amount of the drug leaving the system. Thus, at "steady-state", the patient's body eliminates the drug at approximately the same rate that the drug becomes available to the patient's system through absorption into the blood stream.

[0028] The term "semipermeable wall" for purposes of the present invention means that the wall is permeable to the passage of an exterior fluid, such as aqueous or biological fluid, in the environment of use, including the gastrointestinal tract, but impermeable to drug.

[0029] The term "expandable polymer" for purposes of the present invention means a polymer which upon exposure to an aqueous or biological fluid, absorbs the fluid resulting in a greater mass.

[0030] The term "mean" for purposes of the present invention, when used to define a pharmacokinetic value (e.g., T_{max}) represents the arithmetic mean value measured across a patient population.

[0031] The phrase "pharmaceutically acceptable salt" includes, but is not limited to, metal salts such as sodium salt, potassium salt, cesium salt and the like; alkaline earth metals such as calcium salt, magnesium salt and the like; organic amine salts such as triethylamine salt, pyridine salt, picoline salt, ethanolamine salt, triethanolamine salt, dicyclohexylamine salt, N,N'-dibenzylethylenediamine salt and the like; inorganic acid salts such as hydrochloride, hydrobromide, sulfate, phosphate and the like; organic acid salts such as formate, acetate, trifluoroacetate, maleate, fumarate, tartrate and the like; sulfonates such as methanesulfonate, benzenesulfonate, p-toluenesulfonate, and the like; amino acid salts such as arginate, asparginate, glutamate and the like.

DESCRIPTION OF THE INVENTION

[0032] In certain embodiments of the present invention, the sustained release dosage form provides an in-vitro release rate of oxycodone or a pharmaceutically acceptable salt thereof, when measured by the USP Basket Method at 100 rpm in 900 ml aqueous buffer at a pH of between 1.6 and 7.2 at 37° C. of from 0% to about 40% at 1 hour, from about 8% to about 70% at 4 hours, from about 20% to about 80% at 8 hours, from about 30% to about 95% at 12 hours, from about 35% to about 95% at 18 hrs, and greater than about 50% at 24 hours.

[0033] In certain embodiments of the present invention the time period during which oxycodone blood levels (after administration at steady state) are greater than or equal to 75% of the maximum blood level ($T_{\geq 0.75Cmax}$) may be 4 hours or greater, preferably 6 hours or greater.

[0034] In certain embodiments, the time at which oxycodone blood levels reach their maximum concentration (T_{max}) is about 2 to about 17 hours, preferably about 6.5 hours to about 17 hours, more preferably about 8 to about 16 hours, and even more preferably about 10 to about 16 or about 12 to about 16 hours after administration at steady state of the dosage form.

[0035] In certain embodiments of the present invention, the dosage form provides a C_{24}/C_{max} ratio after administration at steady state of 0.6 to 1.0, a ratio 0.7 to 0.99 or a ratio of 0.8 to 0.95. In other embodiments of the present invention, the dosage form provides a C_{24}/C_{max} ratio after administration at steady state of 0.7 to 1.0, a ratio 0.72 to 0.99 or a ratio of 0.74 to 0.95.

[0036] In certain embodiments of the present invention, the dosage form provides a C_{24}/C_{max} ratio after administration at steady state of 0.6 to 1.0, a ratio 0.7 to 0.99 or a ratio of 0.8 to 0.95 and a (T_{max}) of about 6.5 hours to about 17 hours, about 8 to about 16 hours, about 10 to about 16 hours or about 12 hours to about 16 hours. In other embodiments of the present invention, the dosage form provides a C_{24}/C_{max} ratio after administration at steady state of 0.7 to 1.0, a ratio 0.72 to 0.99 or a ratio of 0.74 to 0.95 and a (T_{max}) in about 2 to about 17 hours.

[0037] In certain embodiments of the present invention, the co-administration of food will not significantly increase or decrease the extent of oxycodone absorption.

[0038] The sustained release oral dosage form of the present invention includes from about 1 to about 640 mg of oxycodone or a pharmaceutically acceptable salt thereof (e.g., oxycodone hydrochloride). Preferably the sustained release oral dosage form of the present invention includes from about 5 to about 500 mg oxycodone or a pharmaceutically acceptable salt thereof, more preferably from about 10 to about 320 mg oxycodone or a pharmaceutically acceptable salt thereof and even more preferably from about 10 to about 160 mg oxycodone or a pharmaceutically acceptable salt thereof.

[0039] In other preferred embodiments, the sustained release dosage form of the present invention comprises from about 10 to about 160 mg oxycodone hydrochloride or an equivalent amount of oxycodone or a pharmaceutically acceptable salt thereof other than the hydrochloride salt.

[0040] The present invention includes a method for administering from about 1 to about 640 mg of oxycodone or a pharmaceutically acceptable salt thereof on a once-a-day basis to a patient in need of relief of pain, in accordance with the pharmacokinetic parameters disclosed herein. Preferably, the method includes administering from about 5 to about 500 mg oxycodone or a pharmaceutically acceptable salt thereof.

[0041] The method of administration according to the present invention is particularly applicable to the treatment of acute and chronic pain, particularly pain associated with terminal disease such as cancer; chronic backpain; and post-operative pain.

Dosage Forms

[0042] In certain embodiments the oral dosage form includes a sustained-release material which is incorporated into a matrix along with the oxycodone or pharmaceutically acceptable salt thereof to provide for the sustained release of the oxycodone. The sustained-release material may be hydrophobic or hydrophilic as desired. The oral dosage form of the present invention may be prepared as granules, spheroids, matrix multiparticulates, etc. which comprise oxycodone or a pharmaceutically acceptable salt thereof in a sustained release matrix, which may be compressed into a tablet or encapsulated. The oral dosage form of the present invention may optionally include other pharmaceutically acceptable ingredients (e.g., diluents, binders, colorants, lubricants, etc.).

[0043] In certain embodiments, the oral dosage form of the present invention may be an osmotic dosage form having a push or displacement composition as one of the layers of a bilayer core for pushing oxycodone or a pharmaceutically acceptable salt thereof from the dosage form, and a semi-permeable wall composition surrounding the core, wherein the wall has at least one exit means or passageway for delivering the oxycodone from the dosage form. Alternatively, the core of the osmotic dosage form may comprise a single layer core including a controlled release polymer and oxycodone or a pharmaceutically acceptable salt thereof.

[0044] Preferably the dosage forms of the present invention provide an analgesic effect for at least about 24 hours after administration.

Sustained-Release Matrix Formulations

[0045] In one preferred embodiment of the present invention, the sustained release carrier may be incorporated into a matrix with the oxycodone or pharmaceutically acceptable salt thereof which matrix provides for the sustained release of the oxycodone.

[0046] A non-limiting list of suitable sustained-release materials which may be included in a sustained-release matrix according to the invention include hydrophilic and/or hydrophobic materials, such as gums, cellulose ethers, acrylic resins, protein derived materials, waxes, shellac, and oils such as hydrogenated castor oil and hydrogenated vegetable oil. However, any pharmaceutically acceptable hydrophobic or hydrophilic sustained-release material which is capable of imparting sustained-release of the oxycodone or pharmaceutically acceptable salt thereof may be used in accordance with the present invention. Preferred sustained-release polymers include alkylcelluloses such as ethylcellulose, acrylic and methacrylic acid polymers and copolymers; and cellulose ethers, especially hydroxyalkylcelluloses (especially hydroxypropylmethylcellulose) and carboxyalkylcelluloses. Preferred acrylic and methacrylic acid polymers and copolymers include methyl methacrylate, methyl methacrylate copolymers, ethoxyethyl methacrylates, ethyl acrylate, trimethyl ammonioethyl methacrylate, cyanoethyl methacrylate, aminoalkyl methacrylate copolymer, poly(acrylic acid), poly(methacrylic acid), methacrylic acid alkylamine copolymer, poly(methyl methacrylate), poly(methacrylic acid)(anhydride), polymethacrylate, polyacrylamide, poly(methacrylic acid anhydride), and glycidyl methacrylate copolymers. Certain preferred embodiments utilize mixtures of any of the foregoing sustained-release materials in the matrix of the invention.

[0047] The matrix also may include a binder. In such embodiments, the binder preferably contributes to the sustained-release of the oxycodone or pharmaceutically acceptable salt thereof from the sustained-release matrix.

[0048] If an additional hydrophobic binder material is included, it is preferably selected from natural and synthetic waxes, fatty acids, fatty alcohols, and mixtures of the same. Examples include beeswax, carnauba wax, stearic acid and stearyl alcohol. This list is not meant to be exclusive. In

certain preferred embodiments, a combination of two or more hydrophobic binder materials are included in the matrix formulations.

[0049] Preferred hydrophobic binder materials which may be used in accordance with the present invention include digestible, long chain (C_8-C_{50}, especially C_{12}-C_{40}), substituted or unsubstituted hydrocarbons, such as fatty acids, fatty alcohols, glyceryl esters of fatty acids, mineral and vegetable oils, natural and synthetic waxes and polyalkylene glycols. Hydrocarbons having a melting point of between 25° and 90° C. are preferred. Of the long-chain hydrocarbon binder materials, fatty (aliphatic) alcohols are preferred in certain embodiments. The oral dosage form may contain up to 80% (by weight) of at least one digestible, long chain hydrocarbon.

[0050] In certain embodiments, the hydrophobic binder material may comprise natural or synthetic waxes, fatty alcohols (such as lauryl, myristyl, stearyl, cetyl or preferably cetostearyl alcohol), fatty acids, including but not limited to fatty acid esters, fatty acid glycerides (mono-, di-, and tri-glycerides), hydrogenated fats, hydrocarbons, normal waxes, stearic acid, stearyl alcohol and hydrophobic and hydrophilic materials having hydrocarbon backbones. Suitable waxes include, for example, beeswax, glycowax, castor wax and carnauba wax. For purposes of the present invention, a wax-like substance is defined as any material which is normally solid at room temperature and has a melting point of from about 30 to about 100° C. In certain preferred embodiments, the dosage form comprises a sustained release matrix comprising oxycodone or a pharmaceutically acceptable salt thereof and at least one water soluble hydroxyalkyl cellulose, at least one C_{12}-C_{36}, preferably C_{14}-C_{22}, aliphatic alcohol and, optionally, at least one polyalkylene glycol. The hydroxyalkyl cellulose is preferably a hydroxy (C_1 to C_6) alkyl cellulose, such as hydroxypropylcellulose, hydroxypropylmethylcellulose and, especially, hydroxyethyl cellulose. The amount of the at least one hydroxyalkyl cellulose in the present oral dosage form may be determined, inter alia, by the precise rate of oxycodone or oxycodone salt release required. The aliphatic alcohol may be, for example, lauryl alcohol, myristyl alcohol or stearyl alcohol. In particularly preferred embodiments of the present oral dosage form, however, the at least one aliphatic alcohol is cetyl alcohol or cetostearyl alcohol. The amount of the aliphatic alcohol in the present oral dosage form may be determined, as above, by the precise rate of oxycodone or oxycodone salt release required. It may also depend on whether at least one polyalkylene glycol is present in or absent from the oral dosage form. In the absence of at least one polyalkylene glycol, the oral dosage form preferably contains between about 20% and about 50% (by wt) of the aliphatic alcohol. When a polyalkylene glycol is present in the oral dosage form, then the combined weight of the aliphatic alcohol and the polyalkylene glycol preferably constitutes between about 20% and about 50% (by wt) of the total dosage form.

[0051] In one preferred embodiment, the ratio of, e.g., the at least one hydroxyalkyl cellulose or acrylic resin to the at least one aliphatic alcoholpolyalkylene glycol determines, to a considerable extent, the release rate of the oxycodone or oxycodone salt from the formulation. In certain embodiments, a ratio of the hydroxyalkyl cellulose to the aliphatic alcohol/polyalkylene glycol of between 1:1 and 1:4 is preferred, with a ratio of between 1:2 and 1:3 being particularly preferred.

[0052] In certain embodiments, the polyalkylene glycol may be, for example, polypropylene glycol, or polyethylene glycol which is preferred. The average molecular weight of the at least one polyalkylene glycol is preferably between 1,000 and 15,000, especially between 1,500 and 12,000.

[0053] Another suitable sustained-release matrix comprises an alkylcellulose (especially ethylcellulose), a C_{12} to C_{36} aliphatic alcohol and, optionally, a polyalkylene glycol.

[0054] In addition to the above ingredients, a sustained-release matrix may also contain suitable quantities of other materials, e.g., diluents, lubricants, binders, granulating aids, colorants, flavorants and glidants that are conventional in the pharmaceutical art.

[0055] In order to facilitate the preparation of a solid, sustained-release oral dosage form according to this invention there is provided, in a further aspect of the present invention, a process for the preparation of a solid, sustained-release oral dosage form according to the present invention comprising incorporating oxycodone or a salt thereof in a sustained-release matrix. Incorporation in the matrix may be effected, for example, by:

[0056] (a) forming granules comprising at least one hydrophobic and/or hydrophilic material as set forth above (e.g., a water soluble hydroxyalkyl cellulose) together with the oxycodone or pharmaceutically acceptable salt thereof;

[0057] (b) mixing the at least one hydrophobic and/or hydrophilic material-containing granules with at least one C_{12}-C_{36} aliphatic alcohol, and

[0058] (c) optionally, compressing and shaping the granules.

[0059] The granules may be formed by any of the procedures well-known to those skilled in the art of pharmaceutical formulation. For example, in one preferred method, the granules may be formed by wet granulating hydroxyalkyl cellulose/oxycodone or oxycodone salt with water. In a particularly preferred embodiment of this process, the amount of water added during the wet granulation step is preferably between 1.5 and 5 times, especially between 1.75 and 3.5 times, the dry weight of the oxycodone or oxycodone salt.

[0060] A sustained-release matrix can also be prepared by, e.g., melt-granulation or melt-extrusion techniques. Generally, melt-granulation techniques involve melting a normally solid hydrophobic binder material, e.g., a wax, and incorporating a powdered drug therein. To obtain a sustained release dosage form, it may be necessary to incorporate a hydrophobic sustained-release material, e.g. ethylcellulose or a water-insoluble acrylic polymer, into the molten wax hydrophobic binder material. Examples of sustained-release formulations prepared via melt-granulation techniques are found, e.g., in U.S. Pat. No. 4,861,598.

[0061] The additional hydrophobic binder material may comprise one or more water-insoluble wax-like thermoplastic substances possibly mixed with one or more wax-like thermoplastic substances being less hydrophobic than said one or more water-insoluble wax-like substances. In order to

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