

INDUSTRIA Y COMERCIO
Radicación : 03097527 00000003 Folios: 2
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Trámite : 011 PCY-PAVEM 270 FASE INCI 536 PETICION
Expediente: 0026 DIVISION DE NUEVAS CREACIONES

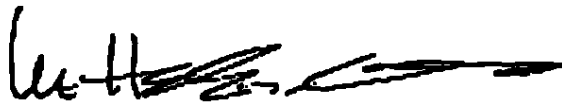
Señores
Superintendencia de Industria y Comercio
División de Nuevas Creaciones
E. S. D.

Ref: Expediente No. 03-097.527
Solicitud de Patente de Invención denominada
"FORMULACIONES DE OXICODONA PARA TOMA
UNA VEZ AL DIA"

Solicitante: EURO CELTIQUE, S.A.

Luz Helena Adarve Gómez, identificado como aparece al pie de mi firma y obrando en mi condición de apoderado de la sociedad EURO CELTIQUE, S.A. solicitante de la patente de invención mencionada en la referencia, solicito al Despacho se sirva proceder con el examen de patentabilidad de esta patente. Para tal fin adjunto el Recibo oficial No. 05-92,353 por un valor de \$371.000.00.

Atentamente,



Luz Helena Adarve Gómez
C.C. 41.575.435 de Bogotá
T.P. 14.884 C.S.J.
Tel No P-222

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SUPERINTENDENCIA Y COMERCIO
Radiacion : 03097527 00000063 folios: 2
Fecha (AMB): 2005-12-06 14:55:12
Trasite : 011 PCT-PATENT 376 FASE NACI 536 PETICION
Dependencia: 8020 DIVISION DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176039-2

RECIBO OFICIAL DE CAJA : 05 - 92.353
FECHA : DICIEMBRE 5 DE 2005

CONSIGNACION

DEPOSITANTE	TIPO PASO	BANCO	CUENTA	No. PASO	FECHA PASO	Vr. PASO
CARCENAS Y CARBENAS P.J. CONSIGNACION		BANCO POPULAR	950-00110-6	36865505	05/12/2005	5.408.700.00

CONCEPTO

CANT. HISTORICO	CONCEPTO	TOTAL CONCEPTO
1 50005-01-01 SOLICITUDES	85 EXAMEN DE PATENTABILIDAD DE INVEN	371,000.00
	TOTAL :	371,000.00

SOL: TRESCIENTOS SETENTA Y UNO MIL PESOS

RESPONSABLE :

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. 03-097.527

CARCENAS & CARBENAS
RECIBO DE CAJA

(91)

DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 03- 97527

EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION

-PCT, FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 553,

DE FECHA 30 DE JUNIO DE 2003, EL TERMINO HABIL SEÑALADO POR LA

LEY EXPIRA EL 27 DE SEPTIEMBRE DE 2005.

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI ☐ ☐

NO ☒ ☐

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

2020/
Bogotá, D.C.,

Doctores
Luz Helena Adarve
Apoderada

03 97527

REFERENCIA	Radicación	03 97527
	Trámite	002
	Evento	001
	Actuación	430
	Folios	016

Como resultado del examen de patentabilidad de la solicitud de patente de invención N° 03 97527, realizado según el artículo 45 de la decisión 486 de la comisión de la Comunidad Andina, se notifica:

Documentos estudiados:

- . Descripción: folios 49-116
- . Ejemplos: folios 116-134
- . Capítulo reivindicatorio estudiado: folios 135-156
- . Se reivindica prioridad presentada en Estados Unidos, el 02.05.01, bajo el número 60/288211

Objeto de la invención

Según las reivindicaciones 1 a 71 de la presente solicitud, se refiere a una forma de dosificación oral de liberación sostenida para aplicación una vez al día que comprende una matriz que comprende oxycodona y un material de liberación sostenida.

Clasificación internacional de patentes A 61 K 31/485

Claridad de la solicitud

El art. 30 de la decisión 486 contempla que "Las reivindicaciones definirán la materia que se desea proteger mediante la patente. Deben ser claras y concisas y estar enteramente sustentadas por la descripción"

El término "cantidad analgésicamente efectiva" de la reivindicación 1 es un término relativo, ya que depende de cada paciente y, por lo tanto, no delimita de manera exacta la materia que desea proteger.

El término "material de liberación sostenido" es muy amplio y puede abarcar materiales que no se encuentran revelados en la descripción.

Las reivindicaciones 1-5, 9, 12-13, 23-28, 32-35, 44-48, 51, 54-56, 65-68 caracterizan a una composición por un resultado de liberación de la misma, lo cual es relativo ya que depende de muchos factores como edad, peso del paciente, etc., haciendo que dichas reivindicaciones no delimiten de manera correcta la materia que se desea proteger.

Favor hacer las aclaraciones y correcciones del caso

Excepciones a la patentabilidad

El artículo 20d de la decisión 486 establece que *"No serán patentables los métodos terapéuticos o quirúrgicos para el tratamiento humano o animal, así como los métodos de diagnóstico aplicados a los seres humanos o a animales"*

El contenido de las reivindicaciones 15-22, 36-43, 57-64, que tratan de "Un método para tratar el dolor...", no es patentable.

El artículo 14 de la decisión 486 de la comisión de la comunidad andina establece que: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*

El contenido de las reivindicaciones 69-71 que tratan de "El uso de una forma de dosis...", no es patentable.

Determinación del estado de la técnica:

Consultadas las fuentes de información con que cuenta este despacho, se encontraron los siguientes documentos, anteriores a la fecha de prioridad de la presente solicitud - 02.05.01-, relacionados con la materia de la presente solicitud:

Nº	Documento	Título	Fecha de publicación
1	WO 9514460	"Formulaciones de opioides para el tratamiento del dolor"	01.06.95
2	EP 0097523	"Composiciones de liberación controlada de acción extendida"	04.01.85
3	EP 0253104	"Bases de liberación controlada para fármacos"	20.01.88

Evaluación de los requisitos de patentabilidad:

El artículo 14 de la decisión 486 de la comisión de la comunidad andina establece que: *"Los países miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*

En cumplimiento del artículo 14 de la decisión 486 de la comisión de la comunidad andina, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

Evaluación de la NOVEDAD

El artículo 16 de la decisión 486 establece que *"Una invención se considerará nueva cuando no esté comprendida en el estado de la técnica"*

La publicación WO 9514480 se relaciona con formulaciones de opioides para el tratamiento del dolor que son aplicadas de forma oral una vez al día, tales composiciones comprenden:

- Un analgésico opioide como la oxycodona
- Un material retardante como un polímero acrílico

La solicitud EP 0097523 publica composiciones orales de liberación extendida de aplicación una vez al día que comprenden:

- Oxycodona
- Una material retardante de la liberación

El documento EP 0253104 enseña composiciones para la liberación extendida de principios activos que comprenden:

- Un ingrediente activo como oxycodona
- Una base retardante de liberación sostenida

La composición de la presente solicitud comprende composiciones que comprenden:

- oxycodona
- un material de liberación sostenida

Comparando elemento por elemento, las composiciones de la presente solicitud son iguales a las de los documentos citados y pueden afectar la novedad de la presente solicitud.

En conclusión los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

Nº	Documento	Reivindicaciones afectadas	Requisito que afecta
1	WO 9514480	1-14, 23-35, 44-56, 65-68	Novedad
2	EP 0097523	1-14, 23-35, 44-56, 65-68	Novedad
3	EP 0253104	1-14, 23-35, 44-56, 65-68	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de la notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

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Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo 5 del título primero de la Circular Única N° 10 de 2001



Álix Camenzá Céspedes de Vergel
Jefe de la División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha 15 JUL 2024

CONCEPTO TÉCNICO Número 0860	EXAMINADOR TÉCNICO Código 202024
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(54) International Patent Classification: A61K 9/14	A1	(11) International Publication Number: WO 95/14460 (43) International Publication Date: 1 June 1995 (95.06.05)
(31) International Application Number: PCT/US94/13606 (32) International Filing Date: 22 November 1994 (94.11.24) (33) Priority Date: 06/156,468 23 November 1993 (93.11.23) US (30) Patent Application or Grant: (35) Related by Continuation US 06/156,468 (2P) Filed on 23 November 1993 (93.11.23) (71) Applicant (for all designated States except US): BURO-CELTIQUE S.A. (LU/LU); 122, boulevard de la Peinasse, L-2330 Luxembourg (LU). (72) Inventors, and (73) Inventor/Applicant (for US only): SACKLER, Richard (US/US); 25 Windsor Way, Greenwich, CT 06830 (US); GOLDENHORN, Paul (US/US); 4 Bald Hill Place, Wilton, CT 06897 (US); KALRO, Robert (US/US); 10 Norfield Wood Road, Weston, CT 06893 (US).	(74) Agent: DAVESSON, Clifford M. et al.; Steinberg Raskin & Davidson, 21st floor, 1140 Avenue of the Americas, New York, NY 10036 (US). (51) Designated States: AM, AT, AU, BR, BG, BE, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GR, HU, JP, KR, KZ, KP, KZ, LX, LB, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TH, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, NG, TD, TG), ARIPO patent (KE, MW, SD, SZ). Published With international search report. <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(59) Title: OPIOD FORMULATIONS FOR TREATING PAIN (57) Abstract Patients are treated with 24-hour oral sustained release opiate formulations which, upon administration, provide an initially rapid opiate absorption such that the minimum effective analgesic concentration of the opiate is more quickly achieved. These sustained release opiate formulations include an effective amount of at least one opiate material to cause said opiate analgesic to be released at such a rate as to provide an analgesic effect after oral administration to a human patient for at least about 24 hours, and are characterized by providing an absorption half-life from 1 to about 4 hours. A method of treating a human patient utilizing these sustained release opiate formulations is also disclosed.		

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WHAT IS CLAIMED IS:

1. An oral sustained release opioid formulation comprising:

5 an opioid analgesic,
 an effective amount of at least one retardant material to cause said opioid analgesic to be released at an effective rate to provide an analgesic effect after oral administration to a human patient for at least about 24
10 hours, said formulation when administered in humans providing an initially rapid rate of rise in the plasma concentration of said opioid characterized by providing an absorption half-life from 1 to about 8 hours in the fasted state.

15 2. The sustained release formulation of claim 1, wherein said oral sustained release provides an absorption half-life from 1 to about 6 hours.

20 3. The sustained release formulation of claim 1, wherein said oral sustained release provides an absorption half-life from 1 to about 3 hours.

25 4. The sustained release formulation of claims 1-3, wherein said opioid analgesic is selected from the group consisting of hydromorphone, oxycodone, dihydrocodeine, codeine, dihydromorphine, morphine, buprenorphine, salts of any of the foregoing, and mixtures of any of the foregoing.

30 5. The sustained release formulation of claims 1-3, wherein said opioid analgesic is selected from the group consisting of alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide, buprenorphine, butorphanol, clonitazene, codeine, cyclazocine, desomorphine, dextromoramide, dezocine, dianpromide, dihydro-
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10. The sustained release formulation of claims 1-3, wherein said opioid analgesic consists of from about 5 mg to about 400 mg oxycodone.

5 11. The sustained release formulation of claims 1-10, which provides a peak plasma level of said opioid in-vivo from about 2 to about 10 hours after administration.

10 12. The sustained release formulation of claims 1-11, wherein said retardant material is selected from the group consisting of an acrylic polymer, an alkylcellulose, shellac, zein, hydrogenated vegetable oil, hydrogenated castor oil, and mixtures of any of the foregoing.

15 13. The sustained release formulation claims 1-12, which comprise a plurality of substrates including said opioid, each of said substrates having a diameter from about 0.5 mm to about 2 mm.

20 14. The sustained release formulation of claim 13, wherein said retardant material is coated on the surface of said substrates.

25 15. The sustained release formulation of claim 13, wherein said substrates comprise inert beads coated with said opioid analgesic, said substrates further comprising an outer coating imparting sustained release properties to said formulation and comprising said retardant material.

30 16. The sustained release formulation of claim 13, wherein said substrates comprise matrices of a substantially uniform mixture of said opioid analgesic and said retardant material.

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gastric fluid, is preferably applied, taking into account the physically characteristics of the therapeutically active agent, the manner of incorporation of the plasticizer, etc. After coating with the hydrophobic polymer, a further overcoat of a film-former, such as Opadry[®], is optionally applied to the beads. This overcoat is provided, if at all, in order to substantially reduce agglomeration of the beads.

Next, the coated beads are cured in order to obtain a stabilized release rate of the therapeutically active agent.

When the coating comprises an aqueous dispersion of ethylcellulose, the coated substrate is preferably subjected to curing at a temperature greater than the glass transition temperature of the coating solution (i.e., ethylcellulose) and at a relative humidity from about 60% to about 100%, until the curing endpoint is reached, e.g., about 60°C and a relative humidity from about 60% to about 100% for a time period from about 48 to about 72 hours, as described in U.S. Patent No. 5,273,760, hereby incorporated by reference.

In preferred embodiments of the present invention directed to the acrylic coating, a stabilized product is obtained by subjecting the coated substrate to oven curing at a temperature above the T_g of the plasticized acrylic polymer for the required time period, the optimum values for temperature and time for the particular formulation being determined experimentally. In certain embodiments of the present invention, the stabilized product is obtained via an oven curing conducted at a temperature of about 45°C for a time period from about 24 to about 48 hours or longer, as described in U.S. Patent No. 5,286,493, hereby incorporated by reference.

The release of the therapeutically active agent from the sustained-release formulation of the present invention

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can be further influenced, i.e., adjusted to a desired rate, by the addition of one or more release-modifying agents, or by providing one or more passageways through the coating. The ratio of hydrophobic polymer to water soluble material is determined by, among other factors, the release rate required and the solubility characteristics of the materials selected.

The release-modifying agents which function as pore-formers may be organic or inorganic, and include materials that can be dissolved, extracted or leached from the coating in the environment of use. The pore-formers may comprise one or more hydrophilic polymers such as hydroxypropylmethylcellulose. The sustained release coatings of the present invention can also include erosion-promoting agents such as starch and gums. The sustained release coatings of the present invention can also include materials useful for making microporous lamina in the environment of use, such as polycarbonates comprised of linear polyesters of carbonic acid in which carbonate groups reoccur in the polymer chain. The release-modifying agent may also comprise a semi-permeable polymer. In certain preferred embodiments, the release-modifying agent is selected from hydroxypropylmethylcellulose, lactose, metal stearates, and mixtures of any of the foregoing. The sustained release coatings of the present invention may also include an exit means comprising at least one passageway, orifice, or the like. The passageway may be formed by such methods as those disclosed in U.S. Patent Nos. 3,845,770; 3,916,889; 4,063,064; and 4,088,864 (all of which are hereby incorporated by reference). The passageway can have any shape such as round, triangular, square, elliptical, irregular, etc.

In other embodiments of the present invention, the present invention may utilize a multiparticulate sustained

(12)

EUROPEAN PATENT APPLICATION

(13) Application number: 8982550.9

(14) Int. Cl. A 61 K 9/26

(15) Date of filing: 21.08.88

(16) Priority: 21.08.82 US 280540

(17) Date of publication of application: 04.01.89 Bulletin 34/1

(18) Designated Contracting States:
AT BE CH DE FR GB IT LI LU NL SE

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(23) Extended action controlled release compositions.

(24) Extended action controlled release compositions are formed by incorporating into a controlled release matrix a medication a mixture of the salt form of the medication and the free base form of the medication preferably in a proportion of 70%-25% by weight of the salt form to 20%-70% by weight of the free base form, the weight amounts being calculated with respect to the active base.

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ingredient is replaced with the base moiety.

When the new slow release compositions are used in therapy, the dosage form may be either a tablet or a capsule and the particular salt-base replacement proportions will depend on the preferred specific therapeutic needs. When it is desired to utilize one-a-day therapy dosage schedules, then it will be found useful to replace 75% of the pharmacologically active salt used as the therapeutic ingredient with the base moiety and in certain instances it may be desired to use even a higher base salt replacement ratio of up to 90% of the amount of the salt used being replaced by the base. The exact proportion of active salt replaced by the base is dependent on the duration of bioavailability desired to be achieved with the particular dosage form. A particular advantage of the present slow release composition is obtained by adjusting the proportion of salt/base active ingredient in slow release pharmaceutical compositions to obtain the desired bioavailability for one-a-day administration schedules of a therapeutic dosage form, without materially modifying tablet size or increasing the amount of active ingredients.

The general method utilized in the production of the composition of the present invention is described below:

To extend further the dissolution time of an active ingredient from a slow release tablet or capsule composition prepared with a pharmacologically active salt, from 25% to 75% of the amount of pharmacologically active salt used in the formula is replaced with the free active base moiety of said salt. When selecting the quantity of the pharmacologically active salt to be replaced with the base, the pharmacologically active portion of the salt enters into such determination. For example, if the active salt used is theophylline

CLAIMS:

1. Extended action controlled release pharmaceutical composition, comprising a pharmaceutically acceptable controlled release core or matrix for pharmaceutically active agents having distributed therethrough a pharmaceutically effective amount of a pharmacologically active substance, said pharmaceutically effective amount comprising a proportion of the salt form of said pharmacologically active substance and a proportion of the free base form of said pharmacologically active substance.
2. A composition as claimed in claim 1, in which from 75 to 25% by weight of the salt form and from 25 to 75% by weight of the free base form are present, the amounts being based on the pharmacological active moiety of the pharmacologically active substance.
3. A composition as claimed in claim 1 or claim 2, characterised in that it is in tablet form.
4. A composition as claimed in claim 1 or claim 2, characterised in that it is in capsule form.
5. A composition as claimed in any of claims 1 to 4, characterised in that the pharmacologically active substance is amitryptaline, atropine, chlorpheniramine, chlorpromizine, codeine, dextrompheniramine, diphenylhydramine, doxilamine, ephedrine, hyoscyamine, morphine, oxycodone, papavarine, phenylpropanolamine, propranolol, quinidine, scopolamine, theophylline or thioridazine.
6. A composition as claimed in any of claims 1 to 5, characterised in that the pharmaceutically effective amount of said pharmacologically active substance comprises between 60% and 40% by weight of the salt form and 40% - 60% by weight of the free base form.

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(i) Publication number: **0 253 104 A1**

(b) **EUROPEAN PATENT APPLICATION**

(c) Application number: **EP107438.1** (d) Int. Cl.: **A61K 8/00, A61K 8/28, A61K 8/52**
(e) Date of filing: **22.05.87**

(f) Priority: 18.07.86 US 887340	(g) Applicant: Euro-Coltique S.A. 122 Boulevard de la Petrusse Luxemburg(LU)
(h) Date of publication of application: 29.01.88 Bulletin 88/02	(i) Inventor: Oehlisch, Benjamin 381 East 84th Street New York 10028(US)
(j) Designated Contracting States: AT BE CH DE ES FR GB GR IT LI LU NL SE	(k) Representative: Klaentli & Speler Mattenstrasse 24 D-8800 Bregenz 1(DE)

(l) **Controlled release bases for pharmaceuticals.**
(m) **The release of therapeutically active agents from controlled release bases is extended by using a combination of a higher aliphatic alcohol and an acrylic resin as the base material.**

EP 0 253 104 A1

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10. Pharmaceutical composition according to claim 1 wherein said pharmaceutical agent is amityp-
teline, atropine, chlorpheniramine, chlorpromazine, codeine, dextropropoxyphene, diphenhydramine, dox-
ylamine, ephedrine, hyoscymine, morphine, oxycodone, papaverine, phenylpropylamine, propranolol,
quinidine, scopolamine, theophylline or thioridazine.

11. Core or matrix for controlled release pharmaceutical compositions for oral administration and being
adapted for distribution therein of a pharmaceutically active agent, said core or matrix comprising a higher
aliphatic alcohol of 10-18 carbon atoms and a pharmaceutically acceptable acrylic resin, said acrylic resin
being in an amount of about 10-60% by weight of the weight of said higher aliphatic alcohol and said acrylic
resin.

12. Core or matrix according to claim 11 wherein the amount of said acrylic resin is about 15-40% by
weight.

13. Core or matrix according to claim 11 wherein the amount of said acrylic resin is about 20-35% by
weight.

14. Pharmaceutical composition according to claim 1 and being in the form of a tablet.

15. Pharmaceutical composition according to claim 1 and being in the form of a caplet.

16. Pharmaceutical composition according to claim 1 and being in capsule form

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This dissolution of the tablets (USP method is described in the previous examples) were as follows:

5 MORPHINE DISSOLVED

	<u>HOUR</u>	<u>FORMULATION A</u>	<u>FORMULATION B</u>
10	1	31.8%	35.7%
	2	48.5%	49.3%
	3	62.6%	55.9%
15	4	72.5%	61.4%
	6	84.3%	66.5%
20	8	100.0%	72.2%
	12	--	82.8%
	18	--	<u>100.0%</u>

We can thus see that when 33% of the cetearyl alcohol is replaced by the acrylic resin that we have an extension of dissolution time from 100% drug release in eight hours to eighteen hours. This extended slow release of morphine would thus make this tablet even suitable for a once a day administration.

While the invention has been illustrated with respect to particular formulations of higher aliphatic alcohol and acrylic resin, and with respect to particular therapeutic agents, it is apparent that variations and modifications thereof can be made without departing from the spirit or scope of the invention. Such modifications are meant to be comprehended within the scope and equivalence of the appended claims.

Claims

1. Extended action controlled release pharmaceutical composition for oral administration, comprising a pharmaceutically active agent distributed in a controlled release core or matrix comprising a higher aliphatic alcohol of 10-18 carbon atoms and a pharmaceutically acceptable acrylic resin, said acrylic resin being in an amount of about 10-60% by weight of the weight of said higher aliphatic alcohol plus the said acrylic resin.

2. Pharmaceutical composition according to claim 1 wherein said acrylic resin is an amount of about 18-40% by weight.

3. Pharmaceutical composition according to claim 1 wherein said acrylic resin is in an amount of about 20-35% by weight.

4. Pharmaceutical composition according to claim 1 wherein said core or matrix also includes a binder.

5. Pharmaceutical composition according to claim 4 wherein said core or matrix also includes a filler.

6. Pharmaceutical composition according to claim 5 wherein said core or matrix also includes a disintegrant.

7. Pharmaceutical composition according to claim 6 wherein said core or matrix also includes a lubricant.

8. Pharmaceutical composition according to claim 1 wherein said core or matrix constitutes about 20-40% by weight of said composition.

9. Pharmaceutical composition according to claim 1 wherein said pharmaceutically active agent is highly water soluble.

