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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S. D.

Ref.: Expediente No. 00.001.049
Solicitud de Patente a nombre de
The Procter & Gamble Company.

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la carrera 11 A No. 94-76, of. 305-306, obrando como apoderada de la sociedad The Procter & Gamble Company, domiciliada en Cincinnati, Ohio, Estados Unidos de América, solicitante de la patente de la referencia, pido a usted que se proceda a examinar si la invención, cuya patente se tramita en el expediente de la referencia, es patentable.

Adjunto al presente memorial el recibo No. 03-72,066 del 2 de octubre 2003, con lo cual queda cubierta la tasa oficial correspondiente a dicho estudio.

Señor Superintendente,

JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
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Cód. 5376

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
ESCOBAR URIBE ASOCIADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	8809846	02/10/2003	11,272,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO		TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	85	EXAMEN DE PATENTABILIDAD DE INVEN	335,000.00
			TOTAL : $	335,000.00

SON: TRESCIENTOS TREINTA Y CINCO MIL PESOS

RESPONSABLE : _____

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SUPERINTENDENCIA

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DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. **00–1049**

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION** FUE PUBLICADO

EN LA GACETA DE PROPIEDAD INDUSTRIAL No **527**, DE FECHA **30** DE **ABRIL** DE **2003**, EL

TERMINO HABIL SEÑALADO POR LA LEY EXPIRA EL **29** DE **JULIO** DE **2003**.

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 ____ **X** _____

Bogotá D.C., Julio 13 de 2004

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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: GELATIN CAPSULES CONTAINING A HIGHLY CONCENTRATED ACETAMINOPHEN SOLUTION

(57) Abstract

A method is disclosed for increasing the solubility of acetaminophen alone or in combination with antihistamines, antitussives, decongestants, and expectorants to form a clear solution for encapsulation into a softgel. The acetaminophen is solubilized alone or in combination with the above ingredients by mixing with polyethylene glycol, propylene glycol, water, polyvinylpyrrolidone and potassium (or sodium) acetate. This invention increases the solubility of the acetaminophen to obtain the same size softgel for a 325 mg dose as is presently available for a 250 mg dose softgel product. The disclosed solvent system is useful because it provides for a highly concentrated solution of acetaminophen capable of encapsulation in a small enough capsule to permit easy swallowing.

WHAT WE CLAIM IS:

1. A soft gelatin capsule for subsequent oral administration having a soft gelatin shell encapsulating a fill, the fill comprising a pharmaceutically acceptable highly concentrated solution of acetaminophen comprising from about 20% to about 40% by weight acetaminophen, from about 18% to about 65% polyethylene glycol by weight, from about 0% to about 15% propylene glycol by weight, from about 0% to about 15% water by weight, from about 0% to about 15% polyvinylpyrrolidone by weight and from about 0.6% to about 25% of an alkali metal acetate by weight, the alkali metal acetate being present in an amount sufficient to increase the maximum solubility of the acetaminophen in the solution.

2. The capsule according to claim 1 wherein the polyethylene glycol has an average molecular weight of between about 200 and about 800.

3. The capsule according to claim 1 wherein the alkali metal acetate is selected from the group consisting of potassium acetate and sodium acetate.

4. The capsule according to claim 1 wherein said alkali metal acetate is present in an amount from about 3% to about 20% by weight.

5. The capsule according to claim 1 wherein the fill additionally comprises a second pharmaceutical agent in addition to acetaminophen, the second pharmaceutical agent being selected from the group consisting of antihistamines, antitussives, decongestants and expectorants.

6. A soft gelatin capsule for subsequent oral administration having a soft gelatin shell encapsulating a fill, the fill comprising a pharmaceutically acceptable highly concentrated solution of acetaminophen comprising from about 20% to about 40% by weight acetaminophen, from about 30% to about 65% polyethylene glycol by weight, from about 0% to about 15% propylene glycol by weight, from about 0% to about 15% water by weight, from about 0% to about 15% polyvinylpyrrolidone by weight and from about 1% to about 25% of an alkali metal acetate by weight, the alkali metal acetate being present in an amount sufficient to increase the maximum solubility of the acetaminophen in the solution.

7. The capsule according to claim 6 wherein the polyethylene glycol has an average molecular weight of between about 200 and about 800.

8. The capsule according to claim 6 wherein the alkali metal acetate is selected from the group consisting of potassium acetate and sodium acetate.

9. The capsule according to claim 6 wherein said alkali metal acetate is present in an amount from about 3% to about 20% by weight.

10. The capsule according to claim 6 wherein the fill additionally comprises a second pharmaceutical agent in addition to acetaminophen, the second pharmaceutical agent being selected from the group consisting of antihistamines, antitussives, decongestants, and expectorants.

11. A soft gelatin capsule for subsequent oral administration having a soft gelatin shell encapsulating a fill, the fill comprising a pharmaceutically acceptable highly concentrated solution of acetaminophen comprising from about 20% to about 40% by weight acetaminophen, from about 18% to about 52% polyethylene glycol by weight, from about 0% to about 12% propylene glycol by weight, from about 0% to about 12% water by weight, from about 0% to about 12% polyvinylpyrrolidone by weight and from about 0.6% to about 20% of an alkali metal acetate by weight, the alkali metal acetate being present in an amount sufficient to increase the maximum solubility of the acetaminophen in the solution.

12. The capsule according to claim 11 wherein the polyethylene glycol has an average molecular weight of between about 200 and about 800.

13. The capsule according to claim 11 wherein the alkali metal acetate is selected from the group consisting of potassium acetate and sodium acetate.

14. The capsule according to claim 1 wherein said alkali metal acetate is present in an amount from about 3% to about 20% by weight.

15. The capsule according to claim 11 wherein the fill additionally comprises a second pharmaceutical agent in addition to acetaminophen, the second

pharmaceutical agent being selected from the group consisting of antihistamines, antitussives, decongestants, and expectorants.

16. A hard shell gelatin capsule for subsequent oral administration having a hard gelatin shell encapsulating a semi-solid or solid fill, the fill comprising a pharmaceutically acceptable highly concentrated solution of acetaminophen comprising from about 20% to about 40% by weight acetaminophen, from about 18% to about 65% polyethylene glycol by weight, from about 0% to about 15% propylene glycol by weight, from about 0% to about 15% water by weight, from about 0% to about 15% polyvinylpyrrolidone by weight and from about 0.6% to about 25% of an alkali metal acetate by weight, the alkali metal acetate being present in an amount sufficient to increase the maximum solubility of the acetaminophen in the solution.

17. The capsule according to claim 16 wherein the polyethylene glycol has an average molecular weight of between about 600 and about 100,000.

18. The capsule according to claim 16 wherein the alkali metal acetate is selected from the group consisting of potassium acetate and sodium acetate.

19. The capsule according to claim 16 wherein the alkali metal acetate is present in an amount from about 3% to about 20% by weight.

20. The capsule according to claim 16 wherein the fill additionally comprises a second pharmaceutical agent in addition to acetaminophen, the second pharmaceutical agent being selected from the group consisting of antihistamines, antitussives, decongestants, and expectorants.

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Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: PROCESS FOR SOLUBILIZING DIFFICULTLY SOLUBLE PHARMACEUTICAL ACTIVES

(57) Abstract

The present invention relates to a process for solubilizing at least one difficultly soluble pharmaceutical active in a mixture of polyethylene glycol and polyvinylpyrrolidone. The process does not require water as a solvent or the use of a heating step. In further embodiments, the present invention also relates to a process for encapsulating these solubilized pharmaceutical compositions within soft gelatin shells, which are preferably transparent. Both the resulting compositions and their capsules provide an effective means for oral delivery of a wide variety of difficultly soluble pharmaceutical actives.

EXAMPLES

The following examples further describe and demonstrate embodiments within the scope of the present invention. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present invention, as many variations thereof are possible without departing from the spirit and scope of the invention.

Ingredients are identified by chemical or CTFA name.

EXAMPLE I

Solubilized Acetaminophen Composition

A highly concentrated solution containing acetaminophen is prepared from the following ingredients.

Ingredient	Weight %
Acetaminophen	26.00
Polyethylene Glycol 600	52.00
Polyvinylpyrrolidone[1]	3.00
Ethanol 95% USP	QS100

[1] Available as Plasdone^{R} K-29/32 from GAF Chemicals Co.

The acetaminophen, polyethylene glycol 600, polyvinylpyrrolidone, and ethanol are combined in a suitable vessel and mixed at room temperature until a homogeneous solution is obtained. Next, the ethanol is removed by rotary evaporation at room temperature. The resulting acetaminophen composition is substantially free from ethanol and water, is suitable for oral administration, and contains about 32.10% acetaminophen, 64.20% polyethylene glycol 600, and about 3.70% polyvinylpyrrolidone.

EXAMPLE II

Soft Gelatin Capsule Containing A Solubilized Acetaminophen Composition

A soft gelatin mixture is first prepared from the following ingredients.

Ingredient	Weight %
Gelatin	47.00
Glycerin	15.00
Water	QS100

The above ingredients are combined in a suitable vessel and heated with mixing at about 65°C to form a uniform solution. Using

standard encapsulation methodology, the resulting solution is used to prepare soft gelatin capsules containing approximately 1000 mg of the acetaminophen composition of Example I. The resulting soft gelatin acetaminophen capsules are suitable for oral administration.

EXAMPLE III

Solubilized Pharmaceutical Composition

A highly concentrated solution containing acetaminophen in combination with other pharmacutical actives is prepared from the following ingredients.

Ingredient	Weight %
Acetaminophen	25.00
Pseudoephedrine Hydrochloride	3.00
Dextromethorphan Hydrobromide	1.49
Doxylamine Succinate	0.38
Polyethylene Glycol 600	46.20
Polyvinylpyrrolidone[1]	2.50
Ethanol 95% USP	QS100

[1] Available as Plasdone^{R} K-29/32 from GAF Chemicals Co.

The acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, doxylamine succinate, polyethylene glycol 600, polyvinylpyrrolidone, and ethanol are combined in a suitable vessel and mixed at room temperature until a uniform solution is formed. Next, the ethanol is removed by rotary evaporation at room temperature. The resulting pharmaceutical composition is substantially free from ethanol and water, is suitable for oral administration, and contains about 31.82% acetaminophen, 3.82% pseudoephedrine hydrochloride, 1.90% dextromethorphan hydrobromide, 0.48% doxylamine succinate, 58.80% polyethylene glycol 600, and 3.18% polyvinylpyrrolidone.

EXAMPLE IV

Soft Gelatin Capsule Containing A Solubilized Acetaminophen Composition

A gelatin solution is prepared as described in Example II. Using standard encapsulation methodology, this gelatin solution is used to prepare soft gelatin capsules containing approximately 1000 mg of the pharmaceutical composition of Example III. The resulting

soft gelatin pharmaceutical capsules are suitable for oral administration.

EXAMPLE V

Solubilized Pharmaceutical Composition

A highly concentrated solution containing acetaminophen in combination with other phamaceutical actives is prepared from the following ingredients.

Ingredient	Weight %
Acetaminophen	23.20
Pseudoephedrine Hydrochloride	2.78
Dextromethorphan Hydrobromide	1.39
Doxylamine Succinate	0.58
Polyethylene Glycol 600	46.47
Polyvinylpyrrolidone[1]	1.86
Propylene Glycol	3.72
Ethanol 95% USP	QS100

[1] Available as Plasdone^{R} K-29/32 from GAF Chemicals Co.

The acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, doxylamine succinate, polyethylene glycol 600, polyvinylpyrrolidone, propylene glycol, and ethanol are combined in a suitable vessel and mixed at room temperature until a homogeneous solution is formed. Next, the ethanol is removed by rotary evaporation. The resulting pharmaceutical composition is substantially free from ethanol and water, is suitable for oral administration, and contains about 29.00% acetaminophen, 3.48% pseudoephedrine hydrochloride, 1.74% dextromethorphan hydrobromide, 0.72% doxylamine succinate, 58.09% polyethylene glycol 600, 2.32% polyvinyl- pyrrolidone, and 4.64% propylene glycol.

EXAMPLE VI

Soft Gelatin Capsule Containing a Solubilized Pharmaceutical Composition

A gelatin solution is prepared as described in Example II. Using standard encapsulation methodology, this gelatin solution is used to prepare soft gelatin capsules containing approximately 1000 mg of the pharmaceutical composition of Example V. The resulting soft gelatin pharmaceutical capsules are suitable for oral administration.

EXAMPLE VII

Solubilized Pharmaceutical Composition

A highly concentrated solution containing acetaminophen in combination with other phamaceutical actives is prepared from the following ingredients.

Ingredient	Weight %
Acetaminophen	22.22
Pseudoephedrine Hydrochloride	2.67
Dextromethorphan Hydrobromide	0.89
Guaifenesin	8.89
Polyethylene Glycol 600	40.00
Polyvinylpyrrolidone[1]	1.78
Propylene Glycol	3.56
Ethanol 95% USP	QS100

[1] Available as Plasdone^{R} K-29/32 from GAF Chemicals Co.

The acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, guaifenesin, polyethylene glycol 600, polyvinylpyrrolidone, propylene glycol, and ethanol are combined in a suitable vessel and mixed at room temperature until a homogeneous solution is formed. Next, the ethanol is removed by rotary evaporation. The resulting pharmaceutical composition is substantially free from ethanol and water, is suitable for oral administration, and contains about 27.77% acetaminophen, 3.34% pseudoephedrine hydrochloride, 1.11% dextromethorphan hydrobromide, 11.11% guaifenesin, 49.99% polyethylene glycol 600, 2.22% polyvinylpyrrolidone, and 4.45% propylene glycol.

EXAMPLE VIII

Soft Gelatin Capsule Containing a Solubilized Pharmaceutical Composition

A gelatin solution is prepared as described in Example II. Using standard encapsulation methodology, this gelatin solution is used to prepare soft gelatin capsules containing approximately 1000 mg of the pharmaceutical composition of Example VII. The resulting soft gelatin pharmaceutical capsules are suitable for oral administration.

EXAMPLE IX

Solubilized Pharmaceutical Composition

A highly concentrated solution containing acetaminophen in combination with other phamaceutical actives is prepared from the following ingredients.

Ingredient	Weight %
Acetaminophen	25.26
Pseudoephedrine Hydrochloride	3.03
Dextromethorphan Hydrobromide	1.52
Chlorpheniramine Maleate	0.20
Polyethylene Glycol 600	43.91
Polyvinylpyrrolidone[1]	2.02
Propylene Glycol	4.04
Ethanol 95% USP	QS100

[1] Available as Plasdone[R] K-29/32 from GAF Chemicals Co.

The acetaminophen, pseudoephedrine hydrochloride, dextromethorphan hydrobromide, chlorpheniramine maleate, polyethylene glycol 600, polyvinylpyrrolidone, propylene glycol, and ethanol are combined in a suitable vessel and mixed at room temperature until a homogeneous solution is formed. Next, the ethanol is removed by rotary evaporation. The resulting pharmaceutical composition is substantially free from ethanol and water, is suitable for oral administration, and contains about 31.58% acetaminophen, 3.79% pseudoephedrine hydrochloride, 1.90% dextromethorphan hydrobromide, 0.25% chlorpheniramine maleate, 54.90% polyethylene glycol 600, 2.53% polyvinylpyrrolidone, and 5.05% propylene glycol.

EXAMPLE X

Soft Gelatin Capsule Containing a Solubilized Pharmaceutical Composition

A gelatin solution is prepared as described in Example II. Using standard encapsulation methodology, this gelatin solution is used to prepare soft gelatin capsules containing approximately 1000 mg of the pharmaceutical composition of Example IX. The resulting soft gelatin pharmaceutical capsules are suitable for oral administration.

WHAT IS CLAIMED IS:

1. A process for solubilizing difficultly soluble pharmaceutical actives, comprising the steps of:

(a) combining and mixing until dissolved

(i) from about 1% to about 40% of at least one difficultly soluble pharmaceutical active, preferably from about 15% to about 35%, most preferably from about 20% to about 30%.

(ii) from about 20% to about 70% of a polyethylene glycol,

(iii) from about 1% to about 28% of a polyvinylpyrrolidone, and

(iv) from about 1% to about 50% of a solvent selected from the group consisting of the monohydric alcohols having from 1 to 4 carbon atoms and mixtures thereof, preferably wherein said solvent is ethanol,

wherein the ratio of said polyethylene glycol to said polyvinylpyrrolidone is at least about 2.5:1; and

(b) evaporating said solvent to obtain a composition containing from about 0.1% to about 6% by weight of said solvent.

2. A process according to Claim 1 wherein said polyethylene glycol is added in an amount from about 30% to about 60% and said polyvinylpyrrolidone is added in an amount from about 1% to about 10% and preferably wherein said polyethylene glycol is added in an amount from about 40% to about 50% and said polyvinylpyrrolidone is added in an amount from about 1% to about 5%.

3. A process according to Claim 2 wherein said difficultly soluble pharmaceutical active is selected from the group consisting of acetaminophen, acetylsalicylic acid, ibuprofen, fenbuprofen,

4. A process according to Claim 3 wherein said polyethylene glycol is selected from the group consisting of PEG-6, PEG-8, PEG-9, PEG-10, PEG-12, PEG-14, PEG-16, PEG-18, PEG-20, and mixtures thereof, preferably wherein said polyethylene glycol is PEG-12; and wherein said polyvinylpyrrolidone has an average molecular weight of about 9,000 to about 45,000, preferably about 29,000.

5. A process according to Claim 1 which further comprises combining in step (a) from about 0.5% to about 20% of a second pharmaceutical active selected from the group consisting of dextromethorphan hydrobromide, doxylamine succinate, pseudoephedrine hydrochloride, chlorpheniramine maleate, guaifenesin, triprolidine hydrochloride, diphenhydramine hydrochloride, and mixtures thereof.

6. A process for preparing soft gelatin capsules of a highly-concentrated liquid, pharmaceutical composition, comprising the steps of:

(a) combining and mixing until dissolved

(i) from about 1% to about 40% of at least one difficultly soluble pharmaceutical active,

(ii) from about 20% to about 70% of a polyethylene glycol,

(iii) from about 1% to about 28% of a polyvinyl-pyrrolidone, and

(iv) from about 1% to about 50% of a solvent selected from the group consisting of monohydric alcohols having from one to four carbon atoms and mixtures thereof, preferably wherein said solvent is ethanol,

wherein the ratio of said polyethylene glycol to said polyvinylpyrrolidone is at least about 2.5:1;

(b) evaporating said solvent to obtain a composition containing from about 0.1% to about 6% by weight of said solvent; and

(c) encapsulating the evaporated composition in a soft

7. A process according to Claim 6 wherein said difficultly soluble pharmaceutical active is selected from the group consisting of acetaminophen, acetylsalicylic acid, ibuprofen, fenbuprofen, fenoprofen, flurbiprofen, indomethacin, naproxen, and mixtures thereof, and preferably wherein said active is acetaminophen.

8. A process according to Claim 7 which further comprises combining in step (a) from about 0.5% to about 20% of a second pharmaceutical active selected from the group consisting of dextromethorphan hydrobromide, doxylamine succinate, pseudoephedrine hydrochloride, chlorpheniramine maleate, guaifenesin, triprolidine hydrochloride, diphenhydramine hydrochloride, and mixtures thereof.

9. A highly-concentrated liquid, pharmaceutical composition prepared in accordance with the process of any of Claims 1-5.

10. A soft gelatin capsule prepared in accordance with the process of any of Claims 6-8.

11. A highly-concentrated liquid, pharmaceutical composition which is substantially free from solvent, comprising:

(a) from about 1.25% to about 50% of at least one difficultly soluble pharmaceutical active;

(b) from about 25% to about 87.5% of a polyethylene glycol;

(c) from about 1.25% to about 35% of a polyvinyl-pyrrolidone; and

(d) from about 0.1% to about 8% water;

wherein the ratio of said polyethylene glycol to said polyvinylpyrrolidone is at least about 2.5:1.

US005350756A

United States Patent [19]

Smith

[11] Patent Number: 5,350,756

[45] Date of Patent: Sep. 27, 1994

[54] **USE OF A CYTOCHROME OXIDASE INHIBITOR TO INCREASE THE COUGH-SUPPRESSING ACTIVITY OF DEXTROMORPHAN**

[76] Inventor: **Richard A. Smith**, 7569 Cabrillo Ave., La Jolla, Calif. 92037

[21] Appl. No.: **890,432**

[22] Filed: **May 28, 1992**

Related U.S. Application Data

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[51] **Int. Cl.**[5] **A61K 31/44**

[52] **U.S. Cl.** **514/289**; 514/295; 514/305

[58] **Field of Search** 514/295, 289, 305, 270

[56] **References Cited**

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5,166,207 11/1992 Smith 514/270

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Primary Examiner—Marianne M. Cintins
Assistant Examiner—T. J. Criares
Attorney, Agent, or Firm—Patrick D. Kelly

[57] **ABSTRACT**

This invention discloses a method for increasing the effectiveness of dextromethorphan (DM) as an antitussive agent (i.e., as a cough suppressant). This method involves the concurrent administration of DM and a second agent which inhibits the oxidative activity of debrisoquin hydroxylase, a cytochrome P450 oxidase enzyme. Effective anti-oxidant compounds include quinidine, yohimbine, and fluoxetine.

6 Claims, 2 Drawing Sheets

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

DIVISION DE NUEVAS CREACIONES

2000-02-24
375

2020
Bogotá, D.C., Febrero 11 de 2005

Doctora
JIMENA ESCOBAR URIBE

ASUNTO	Radicación No.	00 001 049
	Trámite	002
	Evento	001
	Actuación	430
	Oficio No.	12250
	Folios	0

Como resultado del examen de patentabilidad de la solicitud de patente de invención, realizado según lo establece el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se notifica el siguiente concepto técnico:

1. Documentos estudiados

Para el presente estudio se tuvieron en cuenta el capítulo descriptivo comprendido en los folios 4 a 33 y el nuevo capítulo reivindicatorio de los folios 75 a 77 de la solicitud en estudio.

2. Objeto de la Invención

El objeto de la presente solicitud de patente de invención consiste en:

Las reivindicaciones 1 a 14 se refieren a una composición que contiene (a) un compuesto activo (antitusivos, antihistaminas, antihistaminas no sedantes, descongestionantes, expectorantes, analgésicos mucolíticos (?), antiinflamatorios antipiréticos, anestésicos locales ó mezclas de estos); (b) un solvente anhidro hidrófilo miscible con agua (PG, etanol, PEG, carbonato de propileno, monoetiléter de dietilenglicol, poloxamer, glicofurol, glicerol ó mezclas de estos).

La reivindicación 15 se refiere a dextrometorfan.

El problema planteado en esta solicitud es la necesidad de proporcionar composiciones útiles para tratar síntomas asociados con enfermedades respiratorias.

Para resolver este problema técnico la solicitud en estudio proporciona una composición que contiene (a) un compuesto activo y (b) un solvente anhidro hidrófilo miscible con agua.

El objeto de la invención definido anteriormente se clasificó de acuerdo con la

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IPC: A 61 K 9/08 // 47/00 // 31/00 // 31/485 // 47/10.

También se reivindica prioridad de la Solicitud de Patente de los Estados Unidos No. 60 115 378 del 11 de enero de 1999, con respecto a la cual la fecha de presentación de la actual solicitud cumple el plazo máximo permitido.

3. Determinación del Estado de la Técnica

El artículo 16 de la decisión 486 de la comisión de la Comunidad Andina que establece que "*El estado de la técnica comprenderá todo lo que haya sido accesible al publico por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.*

Solo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el articulo 40".

Considerando que la fecha de presentación de la primera solicitud de patente de la cual se reivindica prioridad es 11 de enero de 1999, se consultaron las bases de datos y los archivos con que cuenta la entidad con fecha de publicación anterior y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

No.	Documento	Título	Fecha de Publicación
D1	WO 95 04527	Cápsulas de Gelatina que contienen una solución de acetaminofén altamente concentrada	Feb 16, 1995
D2	WO 93 00072	Proceso para solubilizar activos farmacéuticos poco solubles	Ene 7, 1993
D3	US 5 350 756	Uso de un inhibidor de oxidasa citocromo para aumentar la actividad supresora de la tos de dextrometorfan	Sep 27, 1994

4. 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, se procedió a evaluar el cumplimiento de 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 Art. 16 de la Decisión 486 de la Comisión de la Comunidad Andina

establece: "*Una invención se considerará nueva cuando no está comprendida en el estado de la técnica. El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente, o, en su caso, de la prioridad reconocida.*

Solo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el Art 40".

La reivindicación 15 se refiere a dextrometorfan.

D3 enseña dextrometorfan como un conocido antitusivo (supresor de la tos).

Se observa que el objeto de la reivindicación 15: dextrometorfan, estaba anticipado en D3 que enseña dextrometorfan como un conocido antitusivo (supresor de la tos). De manera que lo solicitado en esta reivindicación no puede ser considerado nuevo.

Evaluación del Nivel Inventivo

El artículo 18 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica.*

Las reivindicaciones 1 a 14 se refieren a una composición que contiene (a) un compuesto activo (antitusivos, antihistaminas, antihistaminas no sedantes, descongestionantes, expectorantes, analgésicos mucolíticos (?), antiinflamatorios antipiréticos, anestésicos locales ó mezclas de estos); (b) un solvente anhidro hidrófilo miscible con agua (PG, etanol, PEG, carbonato de propileno, monoetiléter de dietilenglicol, poloxamer, glicofurol, glicerol ó mezclas de estos).

D1 enseña una composición que contiene (a) un compuesto activo (antitusivos, antihistaminas, descongestionantes, expectorantes, analgésico; (b) un solvente anhidro hidrófilo miscible con agua (PG, PEG).

D2 enseña una composición que contiene (a) un compuesto activo (antitusivos, antihistaminas, descongestionantes, expectorantes, analgésico; (b) un solvente anhidro hidrófilo miscible con agua (PG, Etanol, PEG, Glicerol).

Comparando el objeto de la solicitud: una composición que contiene (a) un compuesto activo y (b) un solvente anhidro hidrófilo miscible con agua con el estado de la técnica: D1 que enseña una composición que contiene (a) un compuesto activo (antitusivos, antihistaminas, descongestionantes, expectorantes, analgésico; (b) un solvente anhidro hidrófilo miscible con agua (PG, PEG); D2 que enseña una composición que contiene (a) un compuesto activo (antitusivos, antihistaminas, descongestionantes, expectorantes, analgésico; (b) un solvente anhidro hidrófilo miscible con agua (PG, Etanol,

PEG, Glicerol); se observa que estos documentos afectan el nivel inventivo porque combinando las composiciones enseñadas en D1 con las composiciones enseñadas en D2, una persona conocedora de la materia puede derivar de forma sencilla la composición de esta solicitud que contiene los mismos principios activos y los mismos solventes de D1 y D2. Es claro entonces que debido a que : (a) la conformación de las composiciones es evidente, a partir de las anterioridades, para una persona conocedora de la materia, (b) las reivindicaciones de esta solicitud no mencionan una característica que conceda un efecto diferente o especial a las composiciones, que pueda considerarse como un aporte a la técnica, así que estas son obvias para una persona versada en la materia y (c) el problema planteado en esta solicitud era la necesidad de proporcionar composiciones útiles para tratar síntomas asociados con enfermedades respiratorias; y puesto que la forma propuesta en esta solicitud para resolver este problema técnico es proporcionar una composición que contiene (a) un compuesto activo y (b) un solvente anhidro hidrófilo miscible con agua, tal como se enseña en D1 y D2; esta solicitud no tiene **nivel inventivo**.

5. Conclusión

En conclusión, los requisitos de patentabilidad de la presente solicitud están afectados así:

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO 95 04527	1 a 14 y 16	Nivel Inventivo
D2	WO 93 00072	1 a 14 y 16	Nivel Inventivo
D3	US 5 350 756	1 a 14 y 16 15	Nivel Inventivo 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.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Unica No. 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista, de fecha 24 FEB. 2005

CONCEPTO TÉCNICO No. 271	EXAMINADOR TÉCNICO Código 202007