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SUPERINDUSTRIA Y COMERCIO
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Fecha (AMD): 2004-08-24 17:34:16
Tramite : 011 PCT-PATENT 379 FASE NACI 538 PETICION
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Señora Jefe de la
DIVISION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

Trámite :**011**
Evento :**379**
Actuación :**538**

Referencia : Expediente No. **03.106.164**

Asunto : Solicitud de patente para **"PREPARACIONES GRANULADAS DE GABOXADOL"**

Solicitante : **H. LUNDBECK A/S**

Publicada en : la Gaceta No. 537 del 27 de febrero de 2004

1. Yo, Emilio FERRERO, identificado como aparece al pie de mi firma, actuando como apoderado en el asunto de la referencia, atentamente, solicito se efectúe el examen de patentabilidad de la solicitud en referencia según lo establecido en el artículo 44 de la Decisión 486 de la Comisión de la Comunidad Andina. Para tal efecto presento junto con este escrito el recibo correspondiente por valor de $177.000.00, que corresponde a la tasa fijada según lo dispuesto en la resolución No. 37323 del 30 de diciembre de 2003.

2. Ruego atentamente a la Señora Jefe se sirva ordenar que se anexe este recibo, para que se efectúe dicho examen y se continúe con el trámite de la solicitud.

Bogotá, 24 AGO. 2004
Señora Jefe,

EMILIO FERRERO
T.P.A. No. 31.929

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DLM/DLM/ID-000207/WPCL3003

61

NIT : 800174089-2 . SUPERINDUSTRIA Y COMERCIO

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CAVELIER ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	23490085	23/08/2004	34,210,600.00

ttttt C O N C E P T O ttttt

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	114 PTC CAP-II EXAMEN DE PATENTIBILID	177,000.00
		TOTAL : $	177,000.00

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RESPONSABLE : _____

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

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Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 01/22941 A1

(54) Title: MELT GRANULATED COMPOSITION AND MODIFIED RELEASE DOSAGE FORM PREPARED FROM SAID COMPOSITION

(57) Abstract: Solid modified release dosage forms, prepared from melt granulated compositions comprising (A) one or more hydrophilic cellulose ether polymers (B) a hydrophilic melt binder and (C) a therapeutically active ingredient

Melt granulated composition and modified release dosage form prepared from said composition

The present invention relates to melt granulated compositions comprising hydrophilic cellulose ether polymers, such as for example, hydroxypropyl methylcellulose as a carrier base material, binder or matrix system, and a hydrophilic melt binder. The melt granulated compositions according to the invention are useful for the preparation of solid modified release dosage forms.

Modified release pharmaceutical preparations have many advantages from a medical viewpoint, i.e. reduction of administration times, better compliance, decrease of side effects and the retention of effective concentration of medical material in the blood.

Hydrophilic cellulose ether polymers such as hydroxypropyl methyl cellulose are particularly useful for the preparation of modified release dosage forms of the matrix type.

The hydrophilic cellulose ether polymer functions as a binder or matrix system to regulate release of components from the dosage form. When administered to a subject and exposed to water, the polymer partially hydrates to form a gelatinous layer, which retard outward diffusion of the therapeutically active ingredient. This original protective gel layer, once formed, permits additional fluid to penetrate into the interior of the dosage device. As the outer gel layer begins to fully hydrate and dissolve, a new layer, which optimally is sufficiently strong to continue to retard outward diffusion, replaces it and thus maintains the modified release features of the dosage form, for the desired length of time.

In order to prepare solid, shaped dosage forms from fine particles or powders, it is generally necessary to process the powders in a manner to improve their flowability thereby enabling the resulting material to be compressed into tablets, encapsulated or molded.

Various granulation processes for improving flowability of powders or other particulate materials, in which the primary particles are bound together with a binder material into larger free-flowing agglomerates or granules, are well known in the art.

One such method is the "wet" granulation process, which is characterised in that the powders are combined with a binder material and moistened with water or an organic solvent under conditions which result in the formation of a wet granulated mass from which the solvent must then be evaporated. The wet granulation process, while widely employed, has certain recognised limitations arising from the use when necessary of non-aqueous solvents which are environmentally deleterious, and furthermore may not be readily adaptable in connection with moisture sensitive medicaments. In particular, wet granulation would not be suitable for granulation of hydrophilic cellulose ether polymers.

An alternative to the "wet" granulation processes is the melt granulation process which comprises the use of room temperature solid or semi-solid materials having a relatively low softening or melting range to promote granulation of powdered or particulate materials, in the substantial absence of added water or other liquid solvents. The low melting solids, when heated to a temperature at or near or the melting range, liquify to act as a binder or granulating medium,which spreads itself over the surface of powdered or particulate materials with which it is associated, and on cooling, forms a solid granulated mass in which the powder or particulate starting materials are bound. An advantage of the melt granulation technique is that it is a "one-pot" granulating technique.

The melt granulated compositions according to the invention are characterised in that the melt binder used for granulation of the hydrophilic cellulose ether polymer is a hydrophilic melt binder, such as polyethylene glycol.

To our knowledge, the only prior art disclosing the use of PEG in the granulation medium for the preparation of modified release formulations is US patent No. 5,403,593. The patent discloses modified release formulations based on a

hydrophilic cellulose ether polymer matrix, which has undergone melt granulation, using a mixture of a lipid and PEG as a melt binder.

It has now been found that solid modified release dosage forms of the matrix type can be prepared from a melt granulated composition of a hydrophilic cellulose ether polymer where a hydrophilic melt binder, such as polyethylene glycol, is used without the addition of a lipid as a melt binder. Surprisingly, the use of a hydrophilic melt binder alone does not alter the release profile of the matrix tablets.

Summary

The present invention thus relates, alone or in combination, to:

A melt granulated, substantially homogeneous compositions comprising:

(A) one or more hydrophilic cellulose ether polymers;

(B) a hydrophilic melt binder; and

(C) a therapeutically active medicament.

Hydrophilic melt binders include, but are not limited to, polyether glycols such as polyethylene glycol and polypropylene glycol, and polyethylene glycol esters or acids, as well as polyoxypropylene and polyethylene oxide, copolymers thereof, and mixtures of the foregoing.

In a particular embodiment of the invention, the hydrophilic melt binder is a polyethylene glycol.

Suitably, the polyethylene glycol used as granulation medium or melt binder has an average molecular weight of about 3,000 to about 9,000. In a particular embodiment, the polyethylene glycol used as a granulation medium is selected from the group

consisting of PEG 3000, PEG 4000, PEG 6000, or PEG 8000.

The term hydrophilic cellulose ether polymer includes but is not limited to hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, sodiumcarboxymethylcellulose, Carbomer, carboxymethylhydroxyethylcellulose, as well as mixtures thereof.

Suitably the hydrophilic cellulose ether polymer used is hydroxypropylmethyl-cellulose, methylcellulose, or mixtures thereof.

According to a particular embodiment of the invention, the hydrophilic cellulose ether polymer is hydroxypropylmethylcellulose.

The hydroxypropylmethylcellulose used according to the invention may have a methoxyl content of about 19 to 30 wt. % and a hydroxypropoxyl content of about 4 to 12 wt. %.

The composition of the invention may also contain various conventional excipients such as binders, diluents, disintegrants, lubricants, etc.

Such diluent or binder materials may be selected from lactose, starches, sodium alginate, dicalcium phosphate (hydrate), sugars, acacia, agar, calcium carrageenan, alginic acid, algin, agarose powder, microcrystalline cellulose, collagen, colloidal magnesium silicate, colloidal silicon dioxide, pectin, gelatin, calcium sulfate, ethyl cellulose and polyacrylates

In one embodiment of the invention, the composition according to the invention comprises:

(A) 10 to 75 wt. % of a hydrophilic cellulose ether polymer or a mixture of hydrophilic cellulose ether polymers

Hydrophilic melt binders include, but are not limited to, polyether glycols such as polyethylene glycol and polypropylene glycol, and polyethylene glycol esters or acids, as well as polyoxypropylene and polyethylene oxide, copolymers thereof, and mixtures of the foregoing, xylitol, acrylate polymers (polymethacrylate).

Polyethylene glycol (PEG) has the generalised formula $HO-(CH_2CH_2O)_n-H$, wherein n represents the average number of oxyethylene groups. PEG, in its commercial forms, generally has a designation corresponding to the average molecular weight of the polymer.

PEG 3000 has a melting point around 48-54°C; PEG 4000 has a melting point around 50-58°C, PEG 6000 has a melting point around 55-63°C and PEG 8000, which is a waxy solid at room temperature, has a melting range around 60-63°C.

While any of the commercially available forms of PEG, which have a melting range above 30 °C, are potentially suitable to prepare formulations of the invention, depending on the ultimate dosage form to be prepared, the preferred PEG polymers for use in the present invention comprise those having an average molecular weight of about 3,000 to about 9,000.

The compositions of the invention may also include various conventional excipients such as binders, diluents, disintegrants, lubricants, etc. well-known to the art.

Examples of conventional diluent or binder materials include lactose, starches, sodium alginate, dicalcium phosphate hydrate, sugars, acacia, agar, calcium carrageenan, alginic acid, algin, agarose powder, microcrystalline cellulose, collagen, colloidal magnesium silicate, colloidal silicon dioxide, pectin, gelatin, calcium sulfate, ethyl cellulose, polyacrylates, etc.

Examples of lubricants include talc, colloidal silicon dioxide, stearic acid, metallic

The composition according to the invention may be added or mixed with conventional excipients such as binders, diluents, disintegrants, lubricants, etc. as defined above, before compression, moulding or encapsulation to form a solid modified release dosage form.

The medicaments to be delivered using the modified release dosage for of the invention include inorganic and organic drugs.

In the examples below, compositions according to the invention has been prepared which comprise Citalopram, Escitalopram and Gaboxadole.

The examples are merely intended to illustrate the invention.

Example 1

Lactose monohydrate was combined with Metolose, Citalopram, HBr and Macrogol in a heat jacketed high shear mixer (Pellmix 1/8). The temperature regulator of the mixer was set to 80 °C and the combined ingredients were blended at 1200 rpm until the product temperature reached about 70 °C. Granulation was continued for 1 to 2 minutes.
Immediately after granulation, the still hot granulate was passed through a 1 mm sieve. Sieving (1 mm sieve) was repeated after cooling. Magnesium stearate was added to the granulate in a Turbulate mixer and blended for 30 s.

The composition of the granulate after addition of magnesium stearate as a lubricant, is given in the table below. The batch size was 1 kg.

Component	% w/w
Escitalopram, oxalat	10.2
PEG 6000	20
Metolose 90SH-15.000	40
Lactose 350 mesh	28.8
Magnesuimstearat (lubricant)	1.0

Table 3: Batch No. EX1153-1/EX1153-2

The granulated product was loaded into a Korsh EK0 tabletting machine mounted with 7 mm convex punches and pressed into tablets.

The properties of the resulting tablets are given in the table below:

Property	Pressure (2 kN)	Pressure (29 N)
Hardness, mean (N)	38 N	66 N
Mass, mean (mg)	130.3 mg	127.8 mg
Friability (Erweka)	0.90 %	1.00 %

Table 4

Example 3

Lactose monohydrate was combined with Metolose, Gaboxadol HCl, and Macrogol in a heat jacketed high shear mixer (Pellmix 1/8). The temperature regulator of the mixer was set to 80 °C and the combined ingredients were blended at 1200 rpm until the product temperature reached about 70 °C. Granulation was continued for 1 to 2 minutes.

Immediately after granulation, the still hot granulate was passed through a 1 mm sieve. Sieving (1 mm sieve) was repeated after cooling. Magnesium stearate was added to the granulate in a Turbulate mixer and blended for 30 s.

The composition of the granulate after addition of lubricant. The batch size was 1 kg.

12. A composition according to claims 9-11 wherein the hydrophilic melt binder is a polyethylene glycol (PEG) with an average molecular weight from about 3,000 to 9,000.

13. A composition according to any of claims 1 to 12 wherein the therapeutically active medicament is Citalopram.

14. A composition according to any of claims 1 to 12 wherein the therapeutically active medicament is Escitalopram.

15. A composition according to any of claims 1 to 12 wherein the therapeutically active medicament is Gaboxadol.

16. A solid modified release dosage form prepared by compression of a composition according to any of claims 1 to 15 or a mixture of a composition according to claims 1 to 15 and conventional pharmaceutical excipients.

17. A modified release dosage form according to claim 16, which is in the form of a tablet.

18. A process for preparing a therapeutically active composition according to claims 1 to 15 comprising:

(I) applying heat to a composition comprising:

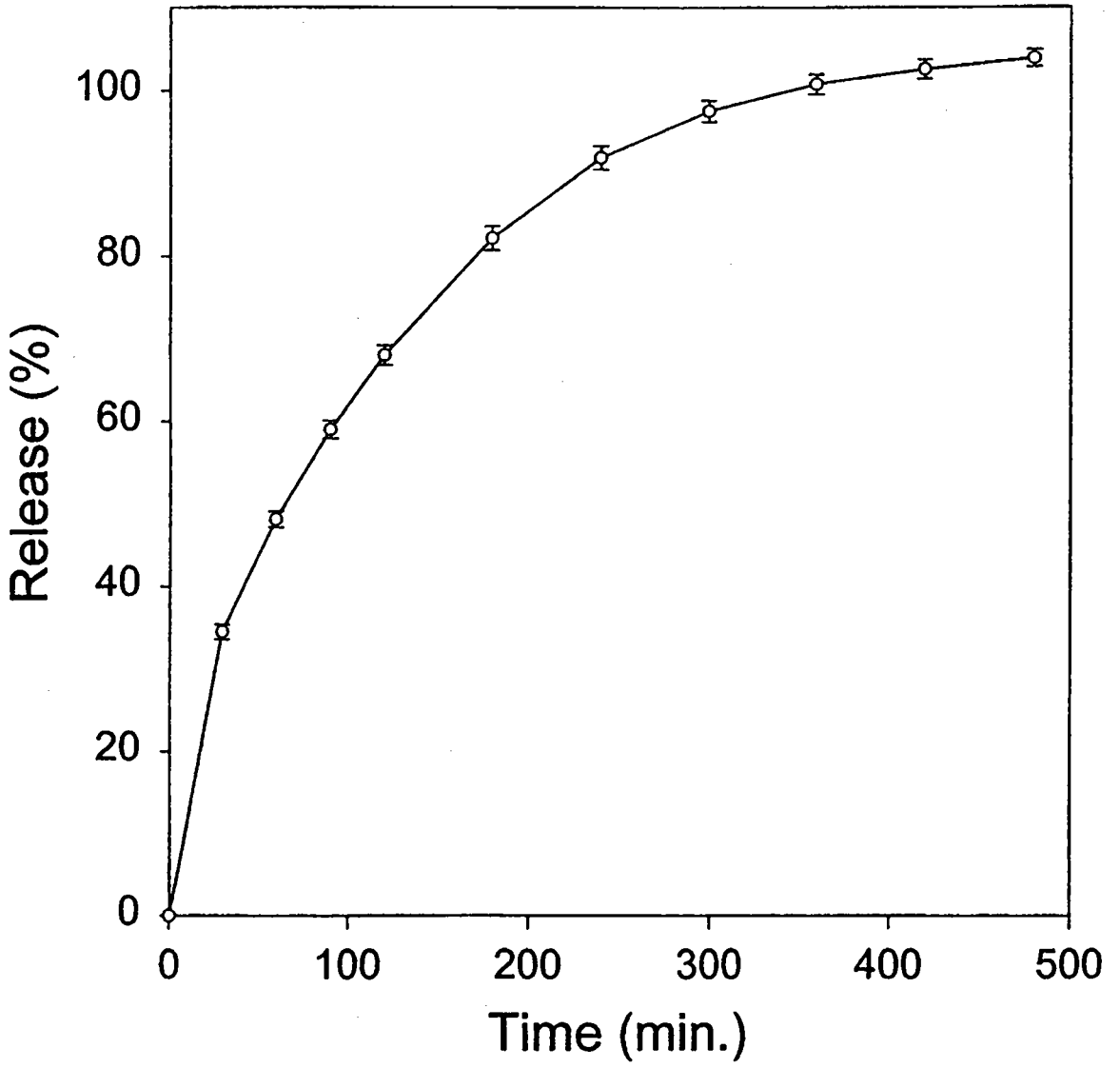
(A) one or more hydrophilic cellulose ether polymers;

(B) a hydophilic melt binder; and

(C) a therapeutically active medicament,

Figure 3

Release Gaboxadol from HPMC matrixtablet



Release (n = 6) from matrixtablet containing
40% Metolose 90SH-15,000

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

202080
Bogotá, D.C., 22.06.2007

Abogado
EMILIO FERRERO
Solicitante: **H. LUNDBECK A/S**

ASUNTO	Radicación	03 106164
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	
	Folios	8525

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

1.1.	Descripción:	Folios 34 a 43
1.2.	Reivindicaciones:	Folios 44 a 46
1.3.	Dibujos:	Folio 35
1.4.	Prioridad:	21 de Mayo de 2001, Dinamarca, PA200100817

2. Objeto de la invención

- Título de la solicitud: PREPARACIONES GRANULADAS DE GABOXADOL

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

- Reivindicaciones de la 1 – 10, 13 y 14: Un producto granulado que contiene Gaboxadol y excipientes
- Reivindicaciones de la 11 - 12: Un proceso de preparación de un producto granulado en fusión que contiene Gaboxadol
- Reivindicaciones 15 - 16: Composición que comprende un producto granulado de acuerdo a con las reivindicaciones anteriores

El problema planteado es esta solicitud es evitar la corrosión de equipos de tableteado fabricados en hierro y acero y además la formación de complejos Gaboxadol-Hierro; el cual se produce por el bajo pH de la solución acuosa de Gaboxadol .

Para solucionar este problema técnico la solicitud en estudio proporciona una composición que contiene excipientes anhidros como lo son el Fosfato de Calcio y el Almidón de Maíz entre otros y emplea un aglutinante no acuoso como lo es el PEG 6000.

- El objeto de la invención definido anteriormente se clasifico de acuerdo con la IPC: A61K9/16, A61K31/4353 y A61P25/20

3. De la solicitud de Patente

3.1. Titulo:

El titulo de la presente solicitud debería ser más especifico en cuanto a la técnica utilizada para la obtención del granulado. Entonces se solicita hacer la corrección pertinente.

3.2. Reivindicaciones *(artículo 30 D 486)*

Faltan Claridad y Concisión en las siguientes reivindicaciones:

Reivindicación 1, 11 y 13: La expresión "Materiales de aporte" no es clara y crea confusión, porque esta no es de común uso en farmacia.
Reivindicaciones 3, 4, 5, 13, 15 y 17: las palabras "Predominantemente" , " Superior", "Convencionales" y "Revestida" son ambiguas por lo tanto no son claras ni concisas.
Reivindicación 6 y 13: Un producto no se puede definir por un proceso de fabricación, ya que esto no genera ni claridad ni concisión; además la 13 no debe depender de las Reivindicaciones 1 – 12 sino de la 1- 10.
Reivindicaciones 11 y 13: los procesos que allí se describen son iguales, lo que crea confusión y falta de claridad.
Reivindicaciones 12 y 14: en estas se caracteriza el proceso por medio de parametros de uno de los excipientes usados; ya que una característica de uno de los excipientes lo define en si y no al proceso.

4. Determinación del Estado de la Técnica

Considerando que la fecha de prioridad es: el 21 de mayo de 2001; se encontraron los siguientes documentos del estado de la técnica relacionados, con fecha de publicación anterior a esta:

N°	Documento	Título	Fecha de Publicación*
D1	WO 01/22941 A1	MELT GRANULATED COMPOSITION AND MODIFIED RELEASE DOSAGE FORM PREPARED FROM SAID COMPOSITION	Abril 05 de 2001

5. Análisis de patentabilidad

5.1. Novedad *(artículo 16 D486)*

Reivindicación 1: Un producto granulado en fusión que contiene Gaboxadol como base libre, como hidrato o como sal de adición de ácido farmacéuticamente aceptable del mismo, así como excipientes y materiales de aporte.

En el D1 se divulga una Composición Farmacéutica que comprende un granulado fundido de Gaboxadol como sal, que se caracteriza porque puede tener: PEG 6000, Almidón, y Fosfato de Calcio dentro de su formulación; como lo indica el documento en su Pagina 3 líneas 14, 27 y 28, Pagina 4 líneas 1,18, 19, 21 y 22, Pagina 8 línea 24, Pagina 11 línea 10, Pagina13 línea 12, Pagina 18 Línea 12 y en la Figura 3.

Los elementos característicos del Producto Reivindicado es decir producto granulado, fundido, que contiene Gaboxadol y que contiene excipientes ya eran conocidos en el D1, así: Granulado fundido Pagina 13 Línea 15, Que contiene Gaboxadol Página 13 Línea 12 y que contiene Excipientes Paginas 13 y 14; por lo tanto el objeto de las Reivindicaciones de la 1 a la 17 no es Novedoso.

El proceso de las Reivindicaciones de la 11 – 12, caracterizado por los pasos de mezclar el principio activo con los excipientes y calentar a una temperatura mayor que el punto de fusión del aglutinante, era conocido previamente D1 Pagina 13, líneas 10 a 19 y página 2, líneas 15 – 28. Por lo cual este no puede considerarse novedoso.

La composición de las Reivindicaciones 15 – 16 que comprende un producto granulado se había divulgado previamente en D1 Página 18 en renglones 11 y 12. Por lo cual no puede considerarse novedoso.

5.2. Nivel inventivo *(artículo18 D486)*

El Estado de la Técnica más cercano es el D1, porque divulga un Producto Granulado de Gaboxadol que sirve para el mismo propósito, el cual es hacer un granulado.

La diferencia con el estado de la técnica más cercano es que en la Reivindicación 4 de esta solicitud se menciona expresamente el almidón de maíz. D1 no dice exactamente que se trata de almidón de maíz, pero está sugerido cuando dice almidones Pagina 4 línea 21.

Esa diferencia no parece conceder un efecto técnico inesperado. El problema técnico planteado en esta solicitud el cual era evitar la corrosión de equipos de tableteado fabricados en hierro y acero y además la formación de complejos Gaboxadol-Hierro; producido por el bajo pH de la solución acuosa de Gaboxadol; se había solucionado previamente en el D1 Pagina 4 Línea 21 porque en él se menciona la inclusión de Almidón dentro del granulado. La mención de estos almidones sugiere el almidón de maíz que se reivindica en esta solicitud. Por esta razón se considera que el granulado reivindicado es evidente para el Experto en la materia.

Considerando que el estado de la técnica divulga previamente un granulado como el reivindicado; el Experto en la Materia motivado por tales sugerencias lograría el producto de la solicitud sin recurrir a actividad inventiva, por lo cual carece de nivel inventivo.

6. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	Documento N°	Reivindicaciones Afectadas	Requisito que Afecta
D1	WO 01/22941 A1	1 a la 17	Novedad y Nivel Inventivo

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 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 capitulo quinto del titulo primero de la Circular Única No. 10 de 2001.

Clara de Jaimes

CLARA CECILIA CASTELLANOS DE JAIMES
Jefe de División de Nuevas Creaciones (E)

El anterior requerimiento fue notificado por fijación en lista, de fecha 13 JUL. 2007

CONCEPTO TECNICO No. 940	**EXAMINADOR TECNICO** Código No. 202080