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A B O G A D O S

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISIÓN DE NUEVAS CREACIONES

E. S. D.

SUPERINTENDENCIA Y COMERCIO
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Ref.: Expediente No. 02-041.350
Solicitud de Patente a nombre de
McNEIL-PPC, INC.

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en Bogotá, en la Carrera 11 A No. 94-76 Of. 305, obrando como apoderada de la sociedad McNEIL-PPC, INC., domiciliada en Skillman, New Jersey, 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. 04 - 53,393 de julio 7, 2004, por la suma de \$353.000.00, 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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JEU/ra.

DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 02-41350

EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 539, DE

FECHA 30 DE ABRIL DE 2004, EL TERMINO HABIL SEÑALADO POR LA LEY

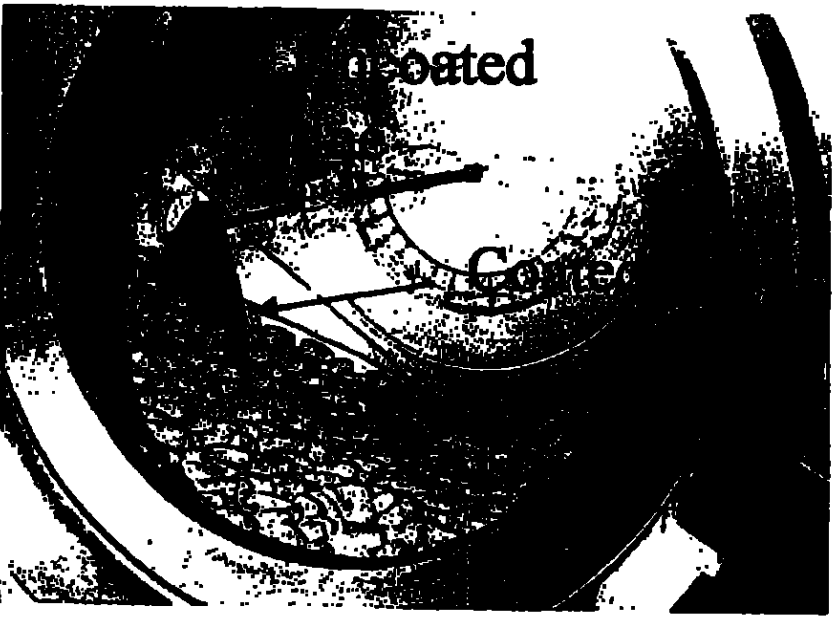
EXPIRA EL 02 DE AGOSTO DE 2004.

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 calga 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** ____

(51) International Patent Classification 6 : B05D 3/02, A61J 3/06, A61K 9/36	A1	(11) International Publication Number: WO 98/30341 (43) International Publication Date: 16 July 1998 (16.07.98)
(21) International Application Number: PCT/US98/04124 (22) International Filing Date: 5 January 1998 (05.01.98) (30) Priority Data: 08/778,944 6 January 1997 (06.01.97) US 09/002,462 2 January 1998 (02.01.98) US (63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 08/778,944 (CIP) Filed on 6 January 1997 (06.01.97) (71) Applicant (for all designated States except GB US): BERWIND PHARMACEUTICAL SERVICES, INC. [US/US]; Moyer Boulevard, West Point, PA 19486 (US). (71) Applicant (for GB only): BPSI HOLDINGS, INC. [US/US]; Suite 1300, 1105 North Market Street, P.O. Box 8985, Wilmington, DE 19899-8985 (US). (72) Inventors; and (73) Inventors/Applicants (for US only): GRILLO, Susan, M. [US/US]; 1042 Bluch Street, Lansdale, PA 19446 (US). KORCHOK, Brian [US/US]; 1811 Supplies Road, Lansdale,		PA 19446 (US). KINSEY, Bruce [US/US]; 436 Store Road, Harleyville, PA 19438 (US). PORTER, Stuart, C. [GB/US]; 675 Brighton Drive, Hatfield, PA 19440 (US). REYES, George [US/US]; 1710 Morris Court, North Wales, PA 19454 (US). BURKE, Thomas, J. [US/US]; Apartment 833, 777 West Germantown Pike, Plymouth Meeting, PA 19462 (US). CUNNINGHAM, Charles [US/US]; 1213 Joseph Road, Ambler, PA 19002 (US). (74) Agents: HARLEY, John, F., A. et al.; Harding, Barley, Follmer & Friley, 86 The Commons At Valley Forge East, 1288 Valley Forge Road, P.O. Box 750, Valley Forge, PA 19482-0750 (US). (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
(34) Title: FILM COATINGS AND FILM COATING COMPOSITIONS BASED ON DEXTRIN		
(57) Abstract		
A dry film coating composition for forming a coating suspension for film coating nutritional supplements, pharmaceutical tablets, and the like, comprising a dextrin and a detackifier.		
		

thereon having a theoretical weight gain of 1.0%.

This produced a film coating on the tablet that possessed an excellent long-lasting shiny gloss, minimal tackiness, good film adhesion, good non-frosty film clarity.

The above-described coating procedure was repeated, except that a 15% solids coating solution/suspension was used, obtained by mixing 30 grams of the formulation of this example into 170 grams of distilled water to form the aqueous coating solution/suspension, and then spraying 20 grams of the solution/suspension onto 1000 grams of color-coated placebos. Again, the resulting coating possessed an excellent long-lasting shiny gloss, minimal tackiness, good film adhesion, and good non-frosty film clarity.

Component	Percentages	Grams
Tapioca Dextrin (A.E. Staley)	70%	700.00
<u>Dextrose</u> (A.E. Staley)	10%	100.00
Mineral Oil (Eastech Chemical Inc.)	10%	100.00
<u>Polyethylene Glycol 8000</u> (Union Carbide)	8%	80.00
Sodium Citrate, Anhydrous (ADM Corn Processing)	<u>2%</u> 100%	<u>20.00</u> 1000

Examples 2-20 further illustrate the invention, all percentages being by weight.

In Examples 2-12, the components of each formulation are mixed together, formed into a coating

suspension, and applied to tablets, as in Example 1, to obtain film coatings possessing long-lasting gloss, good film adhesion, and good film clarity.

EXAMPLE 2

5	<u>Component</u>	<u>Percentages</u>	<u>Grams</u>
	Tapioca Dextrin (A.E. Staley)	72%	720.00
	<u>Dextrose</u> (A.E. Staley)	10%	100.00
	Mineral Oil (Pennreco)	15%	150.00
10	Sodium Citrate, Anhydrous (ADM Corn Processing)	2%	20.00
	<u>Polysorbate 80</u> (ICI Surfactants)	<u>1%</u>	<u>10.00</u>
		100%	1000

15 **EXAMPLE 3**

	<u>Component</u>	<u>Percentages</u>	<u>Grams</u>
	Tapioca Dextrin (A.E. Staley)	72%	720.00
	<u>Dextrose</u> (A.E. Staley)	10%	100.00
	<u>PVP</u> (Pennreco)	5%	50.00
20	Mineral Oil (Pennreco)	10%	100.00
	Sodium Citrate, Anhydrous (ADM Corn Processing)	2%	20.00
	<u>Polysorbate 80</u> (ICI Surfactants)	<u>1%</u>	<u>10.00</u>
25		100%	1000

EXAMPLE 4

	<u>Component</u>	<u>Percentages</u>	<u>Grams</u>
	Tapioca Dextrin (A.E. Staley)	69.5%	695.00
	<u>Dextrose</u> (A.E. Staley)	10%	100.00
30	HPMC E-15 (DOW)	7.5%	75.00

SUBSTITUTE SHEET (RULE 26)

	Mineral Oil (Pennreco)	10%	100.00
	Sodium Citrate, Anhydrous (ADM Corn Processing)	2%	20.00
5	Polysorbate 80 (ICI Surfactants)	<u>1%</u>	<u>10.00</u>
		100%	1000

EXAMPLE 5

	<u>Component</u>	<u>Percentages</u>	<u>Grams</u>
10	Tapioca Dextrin (A.E. Staley)	63.5%	635.00
	Dextrose (A.E. Staley)	10%	100.00
	PVP (Pennreco)	5%	50.00
	Mineral Oil (Pennreco)	10%	100.00
	Glycerin	8%	80.00
15	Sodium Citrate, Anhydrous (ADM Corn Processing)	2%	20.00
	Carnauba Wax (Ross)	<u>1.5%</u>	<u>15.00</u>
		100%	1000

EXAMPLE 6

	<u>Component</u>	<u>Percentages</u>	<u>Grams</u>
20	Tapioca Dextrin (A.E. Staley)	38%	380.00
	Sodium CMC (Aqualon)	18%	180.00
	Dextrose (A.E. Staley)	16%	160.00
	Maltodextrin (A.E. Staley)	16%	160.00
25	Mineral Oil (Pennreco)	10%	100.00
	Sodium Citrate, Anhydrous (ADM Corn Processing)	<u>2%</u>	<u>20.00</u>
		100%	1000

EXAMPLE 7

	<u>Component</u>	<u>Percentages</u>	<u>Grams</u>
30	Tapioca Dextrin (A.E. Staley)	95%	950.00

SUBSTITUTE SHEET (RULE 26)

Claims:

1. A dry film coating composition for forming a coating suspension for film coating nutritional supplements, pharmaceutical tablets, and the like, comprising
a dextrin, and
a detackifier.
2. The composition of claim 1,
the dextrin being tapioca dextrin.
3. The composition of claim 1,
the detackifier being mineral oil, carnauba wax, acetylated monoglyceride, lecithin, magnesium stearate, or a combination thereof.
4. The composition of claim 1,
the dextrin being 5% to 97% by weight of the composition.
5. The composition of claim 1,
the dextrin being 35% to 75% by weight of the composition.
6. The composition of claim 1,
the dextrin being 65% to 75% by weight of the composition.

7. The composition of claim 1,
the detackifier being 1% to 15% by weight of the
composition.

8. The composition of claim 1,
the detackifier being 7.5% to 10% by weight of the
composition.

9. The composition of claim 1, further including
an auxiliary film-former.

10. The composition of claim 9,
the auxiliary film-former being dextrose,
polyvinylpyrrolidone (PVP), hydroxypropyl
methylcellulose, methylcellulose, hydroxypropyl
cellulose (HPC), sodium carboxymethylcellulose (Sodium
CMC), maltodextrin, sodium alginate, PG alginate,
polyvinyl alcohol (PVA), and combinations thereof.

HPMC
HC
HPC
CHCNa⁺

11. The composition of claim 9, the auxiliary
film-former being in a range of greater than 0% to
about 55% by weight of the composition.

12. The composition of claim 9, the auxiliary
film-former being in a range of greater than 3.5% to
about 10% by weight of the composition.

13. The composition of claim 11, the auxiliary

film-former being sodium carboxymethylcellulose (Sodium CMC) in a range of about 40-45% by weight of the composition.

14. The composition of claim 1, further including
a plasticizer.

15. The composition of claim 14,
the plasticizer being polyethylene glycol,
propylene glycol, glycerine, triacetin, acetyltriethyl
citrate, triethyl citrate, tributylcitrate, or
acetyltributylcitrate.

16. The composition of claim 14,
the plasticizer being in a range of greater than
0% to about 15% by weight of the composition.

17. The composition of claim 14,
the plasticizer being in a range of 7.5% to 10% by
weight of the composition.

18. The composition of claim 14,
the plasticizer being in a range of 3.5% to 7.5%
by weight of the composition.

19. The composition of claim 1, further including
a surfactant.

United States Patent [19]

Porter et al.

[11] Patent Number: 4,828,841

[45] Date of Patent: May 9, 1989

[34] MALTODEXTRIN COATING

[75] Inventors: Stuart C. Porter, Hatfield; Edward J. Wernicki, Douglassville, both of Pa.

[73] Assignee: Colorcon, Inc., West Point, Pa.

[21] Appl. No.: 117,796

[22] Filed: Nov. 8, 1987

Related U.S. Application Data

[62] Division of Ser. No. 914,056, Oct. 1, 1986, Pat. No. 4,725,441, which is a division of Ser. No. 633,934, Jul. 24, 1984, Pat. No. 4,643,894.

[31] Int. Cl.⁴ C08L 3/00; C08L 5/00; C09D 3/20

[32] U.S. Cl. 424/479; 106/205; 106/208; 106/210; 106/213; 427/3

[58] Field of Search 424/479; 106/210, 213, 106/205, 208; 427/3

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Primary Examiner—Ronald W. Griffin

Attorney, Agent, or Firm—John F. A. Earley; John F. A. Earley, III

[57]

ABSTRACT

A pharmaceutical, confectionary or food tablet coated on all its exterior surfaces with maltodextrin, which masks the characteristic taste of the tablet ingredients and does not have a slimy taste, with the coating composition comprising maltodextrin, an effective amount of a plasticizer to make the maltodextrin non-brittle and non-cracking when coated onto a tablet, an effective amount of a detachifier for making the maltodextrin and plasticizer non-tacky, a secondary film former to impart gloss and strength to the maltodextrin film coating, and a colorant for imparting color. A method of making tablets coated with maltodextrin.

9 Claims, No Drawings

MALTODEXTRIN COATING

This is a divisional of co-pending application Ser. No. 914,056 filed on 10/1/86, now U.S. Pat. No. 4,725,441, which is a divisional of application Ser. No. 633,934 filed on July 24, 1984, which issued as U.S. Pat. No. 4,643,894 on Feb. 17, 1987.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to the field of coating pharmaceutical, confectionery, and food tablets and the like including medicinal tablets, vitamin tablets, aspirin tablets, capsules, gum balls, and candy pieces.

2. Description of the Prior Art

Film coating of pharmaceutical, confectionery and food tablets with film coating polymers, such as hydroxypropyl methyl cellulose (HPMC), is known. Signorino U.S. Pat. No. 3,981,984 issued Sept. 21, 1976, discloses such coatings and is incorporated herein by reference together with the patents cited therein.

While HPMC and the other film coating polymers known in the art provide effective coatings, they are rather expensive, and have a somewhat disagreeable slimy taste.

SUMMARY OF THE INVENTION

It is an object of this invention to provide a coated pharmaceutical, confectionery and food tablet and the like which is effectively coated with a film coating other than the known film coating polymers such as HPMC.

It is another object to provide such a film coating which is less expensive and which eliminates disagreeable tastes such as a slimy taste.

The objects of the invention are accomplished by providing a coating of maltodextrin modified so that it is non-brittle and non-cracking and forms an effective coating.

The maltodextrin tablet coating of the invention shows enhanced color stability with water soluble dyes, as good as previous tablet coatings made with film forming polymers such as HPMC. Moreover, the maltodextrin tablet coating demonstrated a much greater color intensity than a HPMC system.

Normally, when pigment particles are added to a coating dispersion, the pigment particles weaken the film strength of the polymer film former such as HPMC. Surprisingly, adding pigment particles to the maltodextrin coating dispersion enhances the film strength of the maltodextrin and reduces a cracking of a maltodextrin film coating. This is totally unexpected.

Tablet film coating experts have not recognized maltodextrin as a film coating because of its brittleness and tendency to crack.

As the art of tablet coating moved from sugar to film, the tablet coating lost some of its elegance and gloss. Film coated tablets do not have the high gloss of sugar coated tablets. However, with maltodextrin coated tablets, a high gloss is obtained, higher gloss than film coated tablets and matching that of sugar coated tablets.

The maltodextrin coating also shows high tint strength.

Color pigments are known to give superior color stability in polymer film formers such as HPMC, while soluble dyes give brighter color, but are less stable in HPMC. However, maltodextrin coatings with soluble

dyes have brighter color and more stability than HPMC coatings with soluble dyes. This is unexpected, that maltodextrin soluble dye coatings are more brilliant and more stable than HPMC soluble dye coatings.

The weight gain of the tablet caused by the addition of the maltodextrin coating is about 0.5 to 2.0% on aspirin with 1% being preferred, about 3% on confection tablets, and about 3% on pharmaceutical tablets.

The viscosity of the maltodextrin coating suspension is very low, so although a coating dispersion of 15 parts solids in 85 parts water is preferred, a mixture of 25 to 30 parts solids to 70 to 75 parts water at room temperature is workable for spray coating, and solids loading of 50-60% is obtainable. If you heat the coating suspension, more solid may be added to the maltodextrin coating suspension, which is just the opposite with a HPMC coating suspension. An advantage of using hot maltodextrin coating suspensions is that the air temperature in the spray coating process may be kept below the air temperature required in spray coating with a HPMC coating suspension. This saves energy, and also makes it easier to coat gumballs which are sensitive to heat. Coating gumballs with HPMC coating suspensions may take 4 to 6 hours, while coating gumballs with maltodextrin coating suspensions may take 1 to 1.5 hours.

DETAILED DESCRIPTION

This invention is concerned with coating tablets, which are defined herein as pharmaceutical, confectionery and food tablets including medicinal tablets, vitamin tablets, aspirin tablets, capsules, chewing gum balls, pieces of candy and the like.

In accordance with the method invention, a coating mixture is made of maltodextrin, which acts as a film former in the coating on the tablets, a plasticizer for making the coating non-brittle and non-cracking, and a detackifier for making the coating non-tacky. Other ingredients may include a secondary film former to give a high gloss and strength to the coating on the tablet, and color ingredients to give a desired color to the tablet coating.

The maltodextrin may be Maltrin maltodextrins made by Grain Processing Corp., Muscatine, Iowa, or Amalzo Lo-Dex maltodextrins made by American Maize-Products Company, Hammond, Indiana. By definition, maltodextrins (hydrolyzed cereal solids) are starch hydrolyzates produced by converting pure refined corn starch into nutritive saccharides through the use of acids or specific enzymes. The carbohydrate composition is arranged to yield a DE (dextrose equivalent) of less than 20.

Maltodextrin by itself forms a film coating which is brittle and cracks, so that a tablet coated with maltodextrin is not protected from moisture which may penetrate the coating through the cracks. To prevent brittleness and cracking, a plasticizer is mixed in with the maltodextrin. Suitable plasticizers include hydrogenated glucose syrup (Lycasin by Roquette Corp., Gurnee, Ill.), polyethylene glycol 400, 3350, and 8000 (Carbowax made by Union Carbide), triacetin (triethylcitrate by Pfizer), Citoflex 2 (acetyltriethyl citrate by Pfizer), propylene glycol and glycerine. The plasticizers are used in a range of 3.5 to 15% by weight of the coating mixture, alone or in some combination, with 5 to 10% being preferred. Certain plasticizers cause considerable tackiness during tablet coating, but in combination with another plasticizer used as a detackifier, the tack is considerably reduced or eliminated.

calibrate
-form-pellic
-plastic
-color
-color

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film former about 10%, with 85-98% water, and this coating solution is sprayed onto uncoated aspirin tablets in a conventional coating pan in a chamber with the inlet and outlet air rates and temperature being effective to rapidly evaporate the water and to apply a thin coating of maltodextrin onto the tablets without causing them to decompose or disintegrate.

The coated aspirin tablet of the invention comprises an easily-swallowed, powder-free and gastric-dissintegrable aspirin tablet thinly coated on all exterior surfaces with maltodextrin, with the coating being thin enough not to change significantly the rate of disintegration in the stomach. The coating masks the characteristic taste of aspirin, and smooths the ingestion of the aspirin tablet through the esophagus. In a preferred embodiment the aspirin tablet is uniformly covered with a coating of maltodextrin 60-70%, plasticizer about 10%, detackifier about 10-20%, and secondary film former about 10%.

The following examples illustrate the coated aspirin embodiment of the invention.

EXAMPLE 13

A dry coating mixture is made up as in Example 1 but having the following formula.

70 g maltodextrin (Maltin M150)
10 g polyethylene glycol 400
10 g modified derivatized starch
10 g propylene glycol alginate (Kelcoloid S)
100 g

A coating solution is prepared by suspending 15 parts by weight of the mixture in 85 parts of water by agitation, and aspirin tablets are spray coated as in Example 1.

The maltodextrin 150 is made by Grain Processing Corporation, Muscatine, Iowa, the modified derivatized starch is made by American Malt Products, Hammond, Indiana, the polyethylene glycol 400 is Carbowax by Union Carbide, and the propylene glycol alginate is Kelcoloid S by the Kelco Division of Merck & Company.

EXAMPLE 14

The method of Example 13, except the coating solution is prepared by suspending 2 parts by weight of the mixture into 98 parts of water.

EXAMPLE 15

A coating mixture is made as in Example 1 having the following formula.

60.0 g maltodextrin (Maltin M150)
10.0 g polyethylene glycol 400
20.0 g modified derivatized starch
10.0 g propylene glycol alginate (Kelcoloid S)
100.0 g

A coating solution is made as in Example 13 and aspirin tablets are spray coated as in Example 13.

EXAMPLE 16

A coating mixture is made as in Example 1 having the following formula.

70.0 g maltodextrin (Maltin M150)
10.0 g polyethylene glycol 400
10.0 g crystal gum (tapioca dextrin)
10.0 g propylene glycol alginate (Kelcoloid S)
100.0 g

A coating solution is made as in Example 13 and aspirin tablets are spray coated as in Example 13.

EXAMPLE 17

A coating mixture is made as in Example 1 having the following formula.

60.0 g maltodextrin (Maltin M150)
10.0 g propylene glycol 400
20.0 g crystal gum (tapioca dextrin)
10.0 g propylene glycol alginate (Kelcoloid S)
100.0 g

A coating solution is made as in Example 15 and aspirin tablets are spray coated as in Example 15.

We claim:

1. A film modifier for adding to a primary film-former consisting essentially of powdered particles of film-forming non-toxic edible maltodextrin to make an edible film coating composition, the film modifier comprising a dry mixture obtained by dry blending a plasticizer suitable for making the maltodextrin non-brittle and non-cracking when coated onto a tablet, and an effective amount of a detackifier suitable for making such plasticized maltodextrin non-sticky or non-tacky.
2. The film modifier of claim 1, including an effective amount of secondary film former to impart gloss and strength to the maltodextrin film coating.
3. The film modifier of claim 1, including a colorant for imparting color to the maltodextrin film coating.
4. The film modifier of claim 3, said colorant being titanium dioxide, FD&C lakes, or D&C lakes.
5. The film modifier of claim 3, said colorant being titanium dioxide and a soluble dye.
6. The film modifier of claim 1, the plasticizer being hydrogenated glucose syrup, polyethylene glycol 400, 3350, or 8000, triacetin, acetyltriethyl citrate, propylene glycol or glycerine.
7. The film modifier of claim 1, the detackifier being modified derivatized starch, tapioca dextrin, polyethylene glycol 3350 or 8000.
8. The film modifier of claim 2, the secondary film former being propylene glycol alginate or sodium alginate.
9. A film modifier for adding to a primary film-former consisting essentially of powdered particles of film-forming non-toxic edible maltodextrin to make an edible film coating composition, the film modifier comprising a dry mixture obtained by dry blending a plasticizer suitable for making the maltodextrin non-brittle and non-cracking when coated onto a tablet, and

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an effective amount of a detackifier suitable for making such plasticized maltodextrin non-sticky or non-tacky,
an effective amount of secondary film-former to impart gloss and strength to the maltodextrin film coating, and
a colorant for imparting color to the maltodextrin film coating,
said colorant being titanium dioxide, FD&C lakes, or D&C lakes,

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the plasticizer being hydrogenated glucose syrup, polyethylene glycol 400, 3350, or 8000, triacetin, acetyltriethyl citrate, propylene glycol or glycerine,
the detackifier being modified derivatized starch, tapioca dextrin, polyethylene glycol 3350 or 8000, and
the second film former being propylene glycol alginate or sodium alginate.

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[54] GELATIN COATED CAPLETS AND
PROCESS FOR MAKING SAME

[75] Inventor: Norhart I. Berta, Radnor, Pa.

[73] Assignee: McNellish, Inc., Spring House, Pa.

[21] Appl. No.: 16,914

[22] Filed: Feb. 20, 1987

[51] Int. Cl.⁴ A61K 45/00[52] U.S. Cl. 424/474; 424/463;
424/475; 427/3[58] Field of Search 424/460, 463, 474, 475,
424/454; 427/3; 206/528; 220/8, 20; 604/890.1

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Primary Examiner—Ellis P. Robinson

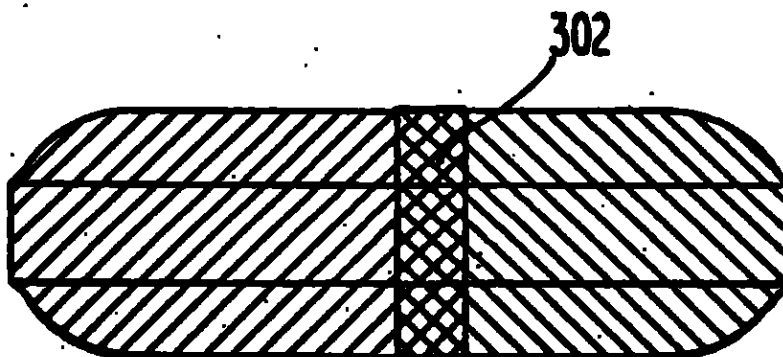
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[57] ABSTRACT

A novel capsule-like medicament, method for producing such medicaments and apparatus are disclosed. The method provides a procedure for coating solid cores, such as caplets, with gelatinous coatings to produce a shiny, capsule-like medicament. Such medicaments are achieved by individually dipping and drying first one end, and then the other end, of each caplet to provide a coating which is smoother and easier to swallow than an uncoated caplet. The production of these capsule-like medicaments is readily facilitated by simple and inexpensive modifications which can be made to existing empty gelatin capsule making equipment.

7 Claims, 5 Drawing Sheets



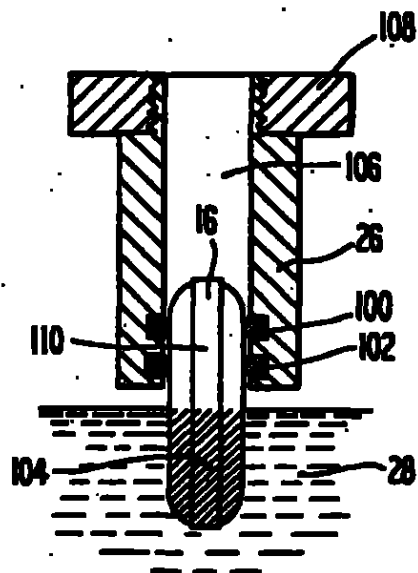


Fig. 2

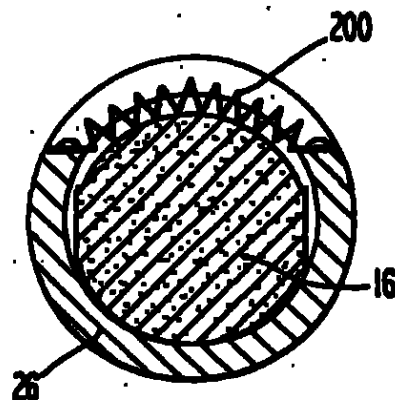


Fig. 5

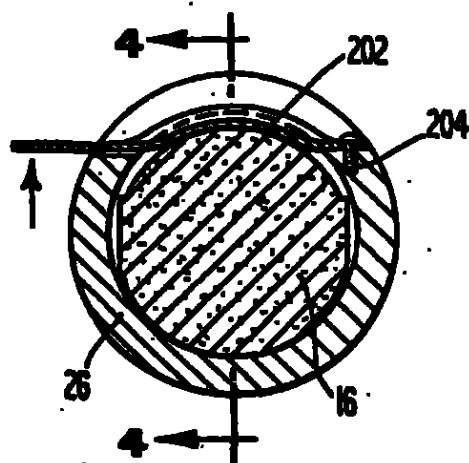


Fig. 3

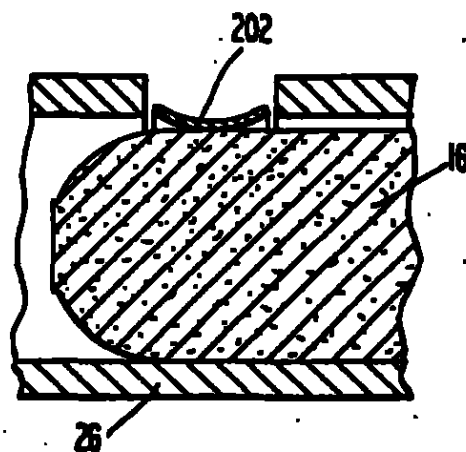


Fig. 4

GELATIN COATED CAPLETS AND PROCESS FOR MAKING SAME

FIELD OF THE INVENTION

This invention relates to coated medicaments and processes for providing gelatinous coverings for such medicaments. This invention is also directed to novel apparatus for producing such medicaments.

BACKGROUND OF THE INVENTION

Until recently, the pharmaceutical industry has relied upon empty gelatin capsules for the encapsulation of medicinal agents as a popular method for administering drugs. Hard capsules are not new. As early as 1848, Murdock introduced the two-piece, hard gelatin capsule. Capsules are tasteless, easily administered and easily filled either extemporaneously or in large quantities commercially. Many patients find it easier to swallow capsules than tablets, therefore preferring to take this form whenever possible. This preference has prompted pharmaceutical manufacturers to market certain products in capsule form even though they are also available in tablet form.

Empty gelatin capsules are typically made from gelatin-glycerin, pure gelatin, starch or sugar gelatin, or other soluble gelatin combinations. See *Ramington's Practice of Pharmacy*, Martin & Cook, 17th edition, pp. 1625-1630, which is herein incorporated by reference. Capsules serve as adequate housings for powders, masses, liquids, pellets and oils and offer improved palatability and convenience.

Generally, empty hard gelatin capsules are manufactured using automated equipment. This equipment employs rows of stainless steel pins, mounted on bars or plates, which are dipped into a gelatin solution maintained at a uniform temperature and fluidity. The pins are then withdrawn from the gelatin solution, are rotated and then inserted into drying kilns through which a strong blast of filtered air with controlled humidity is forced. A crude capsule half is thus formed over each pin during drying. Each capsule half is then stripped, trimmed to uniform length, filled and joined to an appropriate mating half. Such hard capsule making systems are sold by Cherry-Burrell of Cedar Rapids, Iowa.

During most of this century, empty gelatin capsules were a popular dosage form for prescription and over-the-counter (OTC) drugs. However, in the early 1980's there was an unexpected increase in tampering with the contents of these capsules, resulting in several widely publicized deaths. This curtailed consumer demand for these products, caused ubiquitous concern regarding safety among those in the pharmaceutical community, and idled much of the industry's hard capsule making equipment. Improved gelatin capsules and tamper-resistant packaging were then developed, but were expensive to produce and were not foolproof.

Once the threat of capsule tampering was recognized, many manufacturers withdrew their capsule products from the market, often replacing them with solid, oblong-shaped medicaments referred to commonly as caplets. Caplets are solid, oblong tablets which are sometimes coated with material such as cellulose. Typically, this coating is applied using coating-pan systems such as the "Vector-Freund Hi-Coaters", sold by Vector Corporation, 673 44th Street, Marion, Iowa, or the

"GC-1000" sold by Glatt Air Techniques, 20 Spear Road, Ramsey, N.J.

A coating-pan system has a perforated pan or a drum which revolves in a manner similar to a standard clothes dryer. The system includes an air-atomization, spray gun which is inserted into the center of the drum for spraying a fine mist of coating material. A batch of solid medicaments or caplets is typically introduced into the cylindrical pan, wherein said batch is caused to tumble. The tumbling action tends to smooth out some of the rough edges on the caplets prior to coating with organic or aqueous film solutions which may contain solid additives. Coating pans generally produce consistent coating thicknesses and weights but are capable of providing only one color coating. Coatings produced by this method are often thin, offering poor coverage of medicament imperfections and rough edges not removed by the tumbling operation. Unless time is taken to build up a thicker coat, defects on the solid core result in a medicament that does not exhibit a pleasing appearance and may be perceived as being harder to swallow. Moreover, coating abrasion occurring during tumbling produces a surface finish on these medicaments that fails to exhibit the shiny surface that consumers and those in the art have associated with ease of swallowability. Applicant has pan coated caplets with gelatin on an experimental basis and has measured coating thicknesses of only about 6 mils. Moreover, these pan coated gelatin caplets were not observed to be as shiny as caplets coated by a dipping process.

Swallowability, the ability to pass through the fauces, pharynx and esophagus into the stomach, is dependent on the physical characteristics of the medicament as well as psychological factors. See *Stedman's Medical Dictionary*, Anderson Publishing Co., 5th edition, p.1377, which page is herein incorporated by reference. Physical characteristics, such as medicament shape, size and surface finish, can be correlated with esophageal adherence and swallowability. With respect to psychological factors, swallowing is normally volitional in adults, and muscular contractions of the throat are understood to be under the control of the individual at a subconscious level. See *Stedman's*, at 1377. Consumer surveys suggest that a shiny, capsule-like appearance has a special appeal to users as being easier to swallow. In addition, surveys indicate that consumers perceive capsule products to be more effective, thereby adding a possible additional placebo factor to their actual effectiveness.

Solid medicaments comprising gelatin in their coatings have been taught in a number of abstracts. The abstract of J. A. Glassman, U.S. Pat. No. 3,228,786, for instance, is directed to peroral capsules and tablets and a method for manufacturing same. Glassman discloses delayed release, compartmental medicaments with gelatin coatings, and includes treatments for tablets or pellet coatings. The abstract of Japanese Pat. No. 52041213, assigned to Freund Industry Ltd., discloses a process for coating tablets with a solution containing gelatin as a film-forming agent. The abstract of Japanese Pat. No. 69027916, assigned to Sanryo Co. Ltd., is directed to gelatin coated tablets and a process for making same. The process of this patent includes feeding raw tablets at continuous intervals into a support. The tablets are immersed in a coating solution which can comprise gelatin. They are then recovered and held on a holder. Excess coating solution deposited at the lower surface of the tablet is removed by an eliminating plate, and

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finally the tablet is released into a cooling solution from which it is recovered and dried to produce a *seamless* coated tablet. The abstract of Japanese Pat. No. 65009992, assigned to Konishi, is directed to a film-coating method using gelatin for coating tablets in a coating pan. The gelatin described in this abstract is pre-treated with water in a pressure-cooker at a 120°-140° F. for 30-40 minutes to reduce the adhesive properties of the gelatin to allow coating of the tablet. The abstract of Japanese Pat. No. 65009994, also assigned to Konishi, is directed to coating tablets in a coating pan with an emulsion including a mixture of hot water, gelatin, a surface active agent and a member selected from a group consisting of fats and oils, paraffin and wax. The use of the emulsion described in this patent abstract allows tablets to be coated with gelatin in the same manner as coating tablets with sugar. See also the abstract of an article by Richardson entitled "Franciscan Pill Coater", *Pharm. Hkz.*, 28: 90-91 (2)1986. This abstract is directed to the Franciscan Pill Coater, one of the later refinements of the gelatin-coated process that appealed to the practicing pharmacists in the 19th century. Other abstracts also disclosing coatings for solid medicaments comprising gelatin include those for: Japanese Pat. No. 60084215, assigned to Shinetsu Chemical Industries, U.S. Pat. No. 4,238,310, assigned to Lifesavers, Inc., and Japanese Pat. No. 69026677, assigned to Daiichi Seryaku Co. Ltd.

Several patents have disclosed the concept of coating pills by dipping half the surface of the pill at a time. Richards, U.S. Pat. No. 599,865 is directed to a process and apparatus for dipping pills wherein an adhesive bearing bar is used to hold the pills before dipping them into gelatin. This process requires great care in maintaining the consistency of the adhesive material, i.e. wax, so that each pill will adhere to the dipping-bar. The specification of Richards also warns that great care must be taken not to dip the pills so deep as to get any of the gelatin upon the wax, which may ruin its adhesive capacity. The method of Richards additionally is labor intensive, and therefore, is more expensive by today's standards. Clark, U.S. Pat. No. 724,436, is directed to a pill coating machine that employs pill-bars having a series of perforations for receiving pills. Each perforation is adapted for suction, whereby the pill is held in position during the dipping operation. Banker, U.S. Pat. No. 3,896,762, discloses a rotary immersion coating that similarly employs suction to hold solid medicaments prior to passing these medicaments through a coating bath. While Clark and Banker provide apparatus for holding and dipping medicaments, neither discloses that the final product will exhibit a capsule-like appearance with or without a seam. Moreover, applicant has tested vacuum holding apparatus and has discovered that the suction tends to attract some of the gelatin into the holder, producing an irregular seam. Vacuum holding systems such as these also require significant power consumption, are often complicated and uncertain in their action, and necessitate expensive and sensitive vacuum equipment. Finally Oddo, U.S. Pat. No. 3,043,641, discloses apparatus for color-coding tablets that utilizes a rotating resilient roller impregnated with a coating substance, whereby tablets are passed beneath the roller on a conveyor and are deeply impressed into the resilient roller surface. This patent does not disclose the use of gelatin or the use of a dipping process to produce a thick capsule-like coating.

Although these gelatin coated medicaments and processes have achieved some commercial success in the marketplace, a need remains for a coated medicament which is at least as tamper-resistant as a caplet while providing the ease of swallowability of a capsule. There is also a need for a less expensive medicament coating method capable of producing a multi-colored, capsule-like coating which is perceived by the consuming public to be more effective.

SUMMARY OF THE INVENTION

The present invention provides a novel method for coating solid cores, such as caplets, with gelatinous coatings to produce simulated capsule-like medicaments. Such capsule-like medicaments are achieved by individually dipping and drawing first one end and then the other end of each caplet to provide a medicament which is observed to be similar to a regular capsule. The production of such capsules is readily facilitated by simple and inexpensive modifications which may be made to existing, hard capsule, production equipment or by similarly designed newer equipment. In particular, the preferred apparatus of the present invention replaces the prior art steel pins of a standard capsule production machine with novel caplet holding means having caplet channels therein for receiving, individually gripping and transferring caplets during various stages of the herein described coating process. Also included, are novel caplet designs which readily facilitate the method of this invention. As a result, novel capsule-like medicaments are provided having smooth, relatively thick, shiny, multi-colored gelatinous coatings thereon. These medicaments are pleasing to the eye, and should be perceived by consumers as easier to swallow and more effective than prior art caplet medicaments, while providing much greater tamper resistance than conventional capsules.

It is, therefore, an object of this invention to provide a simulated, capsule-like medicament having a gelatinous coating capable of being provided in two or more colors.

It is another object of this invention to provide a simulated, capsule-like medicament that is tamper-resistant.

It is another object of this invention to provide a simulated, capsule-like medicament that provides greater ease in swallowing and is perceived to be more effective than pan-coated pharmaceutical equivalents.

It is still another object of this invention to provide a novel and less expensive method and apparatus for adapting existing hard capsule equipment for manufacturing gelatin coated caplets.

It is still another object of this invention to provide a heavy layer of gelatin as a single coating to cover imperfections inherent on the caplet core.

With these and other objects in view, which will become apparent to one skilled in the art as the description proceeds, this invention resides in the novel construction, combination, arrangements of parts and methods substantially as hereinafter described and more particularly defined by the attached claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate a complete embodiment of the invention according to the best mode so far devised for the practical application of the principles thereof, and in which:

SUPERINTENDENCIA DE INDUSTRIA Y C MERCIO
DIVISION DE NUEVAS CREACIONES

2020
Bogotá, D.C., Septiembre 12 de 2006

Abogada
JIMENA ESCOBAR URIBE

ASUNTO	Radicación No.	02 041 350
	Trámite	002
	Evento	001
	Actuación	430
	Oficio No.	10975
	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:

Título de la solicitud: "Composiciones de recubrimiento por inmersión que contienen almidón ó dextrina".

1. Documentos estudiados

Para el presente estudio se tuvieron en cuenta el capítulo descriptivo comprendido en los folios 9 - 78 y el capítulo reivindicatorio de los folios 79 – 89 de la solicitud.

2. Objeto de la invención

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

Las reivindicaciones 1 – 10, 18, 20, 21, 28, 32 - 35, se refieren a una composición formadora de película para cubrir un sustrato por inmersión, formada por:

- Formador de película (almidón, dextrina, derivados, mezclas)
- Espesante (dextrosa, fructosa ó sus mezclas)
- Plastificante (PEG, glicerina, sorbitol, citrato trietilico, citrato de tributilo, sebacato de dibutilo, aceites vegetales, tensioactivos, propilenglicol, mono-, di- ó tri- acetato de glicerol, gomas naturales, aceite de castor y sus mezclas) y
- Opcionalmente Intensificador de peso (simeticona, polisorbato 80, mezclas) y Colorante (azo, quinofalona, trifenilmetano, xantano, indigolde, óxido de hierro, dióxido de titanio, naturales ó mezclas).

Las reivindicaciones 11 – 17, 19, 23, 29, 30 se refieren a una forma de dosificación que tiene núcleo, una película de sub-recubrimiento sobre este y un recubrimiento exterior de la reivindicación 2.

La reivindicación 19 se refiere a una forma de dosificación que satisface los

requisitos de disolución de la USP.

La reivindicación 22 se refiere al método de hacer tabletas recubiertas que consiste en recubrirlas por inmersión, en condiciones suficientes.

Las reivindicaciones 24, 27, 31 se refieren a un medicamento simulado (¿?).

El problema planteado en esta solicitud es la necesidad de un recubrimiento con resistencia, plasticidad, dureza, espesor adecuados que se adhieran bien al sustrato, con dispersión uniforme de color y apariencia estética sin rugosidad, con brillo y espesor uniforme; para sustratos tales como tabletas y cápsulas.

Para resolver este problema técnico la solicitud en estudio proporciona una composición para cubrir un sustrato por inmersión, formada por: Formador de película (almidón, dextrina, derivados, mezclas) y Espesante (dextrosa, fructosa ó sus mezclas).

El objeto de la invención definido anteriormente se clasificó de acuerdo con la IPC: A 61 K 9/16 // 9/20 // 9/48 // 9/50.

También se reivindica prioridad de las Solicitudes de Patente de los Estados Unidos US 60 291 127 de mayo 15 de 2001, US 60 325 726 de septiembre 28 de 2001, US 10 122 999 de Abril 12 de 2002 y 10 122 531 de Abril 15 de 2002, con respecto a las cuales la fecha de presentación de la actual solicitud cumple el plazo máximo permitido.

3. Con respecto a los Art. 28 y 30 de la D 486

El artículo 28 de la Decisión 486 establece: *"La descripción deberá divulgar la invención de manera suficientemente clara y completa para su comprensión y para que una persona capacitada en la materia técnica correspondiente pueda ejecutarla. La descripción de la invención indicará el nombre de la invención e incluirá la siguiente información:*

- a) el sector tecnológico al que se refiere o al cual se aplica la invención;*
- b) la tecnología anterior conocida por el solicitante que fuese útil para la comprensión y el examen de la invención, y las referencias a los documentos y publicaciones anteriores relativas a dicha tecnología;*
- c) una descripción de la invención en términos que permitan la comprensión del problema técnico y de la solución aportada por la invención, exponiendo las diferencias y eventuales ventajas con respecto a la tecnología anterior;*
- d) una reseña sobre los dibujos, cuando los hubiera;*
- e) una descripción de la mejor manera conocida por el solicitante para ejecutar o llevar a la práctica la invención, utilizando ejemplos y referencias a los dibujos, de ser éstos pertinentes; y,*
- f) una indicación de la manera en que la invención satisface la condición de ser susceptible de aplicación industrial, si ello no fuese evidente de la descripción o de la naturaleza de la invención.*

El artículo 30 de la Decisión 486 establece: *"Las reivindicaciones definirán la materia que se desea proteger mediante la patente. Deben ser claras y concisas y estar enteramente sustentadas por la descripción.*

Las reivindicaciones podrán ser independientes o dependientes. Una reivindicación será independiente cuando defina la materia que se desea proteger sin referencia a otra reivindicación anterior. Una reivindicación será dependiente cuando defina la

materia que se desea proteger refiriéndose a una reivindicación anterior. Una reivindicación que se refiera a dos o más reivindicaciones anteriores se considerará una reivindicación dependiente múltiple”.

La descripción divulga la invención de manera suficientemente clara y completa para su comprensión, tal como lo establece el Art 28 de la decisión 486 de la Comisión Andina. Menciona el sector tecnológico al que pertenece, los antecedentes de la técnica, la divulgación del problema técnico, la solución propuesta y la ventaja frente a la tecnología anterior.

Pero en cuanto a la reivindicación 19 se observa que esta no define la forma de dosificación porque menciona que “satisface los requisitos de disolución de la USP”, lo cual no la caracteriza. Se recuerda que el resultado a alcanzar no es una característica técnica de la invención. Las reivindicaciones deben definir la invención por sus características esenciales, en este caso por medio de los componentes que son nuevos. La invención no queda definida por el resultado a alcanzar (tal como “satisface los requisitos de disolución de la USP”), puesto que la reivindicación incluiría no sólo la solución propuesta por el solicitante, sino todas las alternativas presentes o futuras que lleguen a ese resultado. Debe hacerse la corrección necesaria.

Respecto a las reivindicaciones 24, 27, 31, que se refieren a un medicamento simulado (?); se observa que no mencionan en forma clara y ordenada los compuestos que caracterizan al medicamento. De otro lado, la expresión “medicamento simulado” no es conocida en la técnica. Debe hacerse claridad al respecto.

La reivindicación 22 se refiere al método de hacer tabletas recubiertas que consiste en recubrirlas por inmersión, en condiciones suficientes. Se observa que el método no menciona todos los pasos que lo hacen novedoso, ni las condiciones específicas en que ellos se realizan. Se limita a decir que es “por inmersión” y agrega que “en condiciones suficientes”, lo cual no es una característica que defina inequívocamente al método reivindicado. Se solicita hacer la aclaración correspondiente.

4. Orden

Aunque no existe una legislación al respecto, sería recomendable presentar el capítulo reivindicatorio de forma organizada. El desorden se presenta porque empieza en las reivindicaciones 1 – 10, que se refieren a una composición para cubrir un sustrato, salta a las 18, 20, 21, 28, y luego a las 32 - 35. Continúa con las reivindicaciones 11 – 17, que se refieren a una forma de dosificación y luego salta a las reivindicaciones 19, 23, 29, 30. Como se observa, no hay una secuencia clara en la forma en que se presenta el capítulo reivindicatorio.

5. 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 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 artículo 40°.

Considerando que la fecha de presentación de la primera solicitud de patente de la cual se reivindica prioridad es mayo 15 de 2001, 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 98 30341	Film Coatings And Film Coating Compositions Based On Dextrin	Jul 16, 1998
D2	US 4 828 841	Maltodextrin coating	Mayo 9, 1989
D3	US 4 820 524	Gelatin coated caplets and process for making same	Abr 11, 1989

6. 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°.

Las reivindicaciones 1 – 10, 18, 20, 21, 28, 32 - 35, se refieren a una composición formadora de película para cubrir un sustrato por inmersión, formada por:

- Formador de película (almidón, dextrina, derivados, mezclas)
- Espesante (dextrosa, fructosa ó sus mezclas)
- Plastificante (PEG, glicerina, sorbitol, citrato trietilico, citrato de tributilo, sebacato de dibutilo, aceites vegetales, tensioactivos, propilenglicol, mono-, di- ó tri- acetato de glicerol, gomas naturales, aceite de castor y sus mezclas) y
- Opcionalmente Intensificador de peso (simeticona, polisorbato 80, mezclas) y Colorante (azo, quinofalona, trifenilmetano, xantano, Indigolde, óxido de hierro, dióxido de titanio, naturales ó mezclas).

Las reivindicaciones 11 – 17, 19, 23, 29, 30 se refieren a una forma de dosificación que tiene núcleo, una película de sub-recubrimiento sobre este y un recubrimiento exterior de la reivindicación 2.

La reivindicación 22 se refiere al método de hacer tabletas recubiertas que consiste en

recubrirías por inmersión, en condiciones suficientes.

D1 enseña una composición formadora de película para cubrir un sustrato por inmersión, compuesta por:

- Formador de película (almidón, dextrina, derivados, mezclas)
- Espesante (dextrosa, alginato, PVA, PVP, HPMC, MC, HPC, CMC)
- Plastificante (PEG, glicerina, citrato trietilico, citrato de tributilo, aceites, tensioactivos, propilenglicol,) y
- Opcionalmente Intensificador de peso (polisorbato 80) y Colorante

D2 enseña una composición formadora de película para cubrir un sustrato por inmersión, compuesta por:

- Formador de película (maltodextrina, almidón)
- Espesante (alginato)
- Plastificante (PEG, PG, glicerina, tensioactivos) y
- Opcionalmente Colorante

D3 enseña el método de hacer capletas recubiertas que consiste en recubrirías por inmersión. La figura 2 presenta la forma como se sostiene la tableta y se sumerge en el material de recubrimiento. Se explica que después de dejar secar, se recubre con otra capa y luego se realiza el mismo proceso con el otro extremo de la capleta que aún no ha sido recubierto.

Se observa que los elementos característicos de las composiciones reivindicadas formadoras de película para cubrir un sustrato por inmersión es decir: Formador de película (almidón, dextrina, derivados, mezclas) y Espesante (dextrosa, fructosa ó sus mezclas), ya eran conocidos en D1 y D2; por lo cual no pueden considerarse nuevas. De la misma manera, el método de recubrir capletas por inmersión, se conocía en D3, así que no es 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 – 10, 18, 20, 21, 28, 32 - 35, se refieren a una composición formadora de película para cubrir un sustrato por inmersión, formada por:

- Formador de película (almidón, dextrina, derivados, mezclas)
- Espesante (dextrosa, fructosa ó sus mezclas)
- Plastificante (PEG, glicerina, sorbitol, citrato trietilico, citrato de tributilo, sebacato de dibutilo, aceites vegetales, tensioactivos, propilenglicol, mono-, di- ó tri- acetato de glicerol, gomas naturales, aceite de castor y sus mezclas) y
- Opcionalmente Intensificador de peso (simeticona, polisorbato 80, mezclas) y Colorante (azo, quinofalona, trifenilmetano, xantano, indigoide, óxido de hierro, dióxido de titanio, naturales ó mezclas).

Las reivindicaciones 11 – 17, 19, 23, 29, 30 se refieren a una forma de dosificación que tiene núcleo, una película de sub-recubrimiento sobre este y un recubrimiento exterior de la reivindicación 2.

La reivindicación 22 se refiere al método de hacer tabletas recubiertas que consiste en recubrirías por inmersión, en condiciones suficientes.

D1 enseña una composición formadora de película para cubrir un sustrato por inmersión, compuesta por:

- Formador de película (almidón, dextrina, derivados, mezclas)

- Espesante (dextrosa, alginato, PVA, PVP, HPMC, MC, HPC, CMC)
- Plastificante (PEG, glicerina, citrato trietilico, citrato de tributio, aceites, tensioactivos, propilenglicol,) y
- Opcionalmente Intensificador de peso (polisorbato 80) y Colorante

D2 enseña una composición formadora de película para cubrir un sustrato por inmersión, compuesta por:

- Formador de película (maltodextrina, almidón)
- Espesante (alginato)
- Plastificante (PEG, PG, glicerina, tensioactivos) y
- Opcionalmente Colorante

D3 enseña el método de hacer capletas recubiertas que consiste en recubrir las por inmersión. La figura 2 presenta la forma como se sostiene la tableta y se sumerge en el material de recubrimiento. Se explica que después de dejar secar, se recubre con otra capa y luego se realiza el mismo proceso con el otro extremo de la capleta que aún no ha sido recubierto.

Se observa que:

- debido a que los **compuestos** que integran la composición formadora de película para cubrir un sustrato por inmersión, es decir: *Formador de película (almidón, dextrina, derivados, mezclas)* y *Espesante (dextrosa, fructosa ó sus mezclas)*; eran conocidos en las anterioridades, una persona de habilidades ordinarias en el arte los adaptaría fácilmente a la preparación de la composición de recubrimiento reivindicada en esta solicitud;
- las reivindicaciones de esta solicitud no mencionan una característica que conceda un efecto diferente o especial a la composición formadora de película para cubrir un sustrato por inmersión conformada por: *Formador de película (almidón, dextrina, derivados, mezclas)* y *Espesante (dextrosa, fructosa ó sus mezclas)*, que pueda considerarse como un aporte a la técnica, así que es obvia para una persona versada en la materia;
- el problema planteado en esta solicitud que era la necesidad de un recubrimiento con resistencia, plasticidad, dureza, espesor adecuados que se adhiriera bien al sustrato, con dispersión uniforme de color y apariencia estética, sin rugosidad, con brillo y espesor uniforme; para sustratos tales como tabletas y cápsulas, se resuelve proporcionando una composición para cubrir un sustrato por inmersión, formada por: *Formador de película (almidón, dextrina, derivados, mezclas)* y *Espesante (dextrosa, fructosa ó sus mezclas)*, es decir de la misma manera como se resolvía en las anterioridades;
- el resultado obtenido: es decir composición para cubrir un sustrato por inmersión, formada por: *Formador de película (almidón, dextrina, derivados, mezclas)* y *Espesante (dextrosa, fructosa ó sus mezclas)* no es inesperado.
- no parece haberse superado un prejuicio técnico anterior, con la composición para cubrir un sustrato por inmersión, formada por: *Formador de película (almidón, dextrina, derivados, mezclas)* y *Espesante (dextrosa, fructosa ó sus mezclas)*, propuesta de manera que el objeto reivindicado no tiene nivel inventivo.

7. Conclusión

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

Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO 98 30341	1 - 10, 18, 20, 21, 28, 32 - 35 11 - 17, 19, 23, 29, 30	Novedad y Nivel inventivo
D2	US 4 828 841	1 - 10, 18, 20, 21, 28, 32 - 35 11 - 17, 19, 23, 29, 30	Novedad y Nivel inventivo
D3	US 4 820 524	22	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 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 CESPÉDES DE VERGEL
 Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista, de fecha
12-8 SET. 2006

CONCEPTO TÉCNICO No. 1457	EXAMINADOR TÉCNICO Código 202007
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Item	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO 98 30341	1 – 10, 18, 20, 21, 28, 32 – 35 11 – 17, 19, 23, 29, 30	Novedad y Nivel inventivo
D2	US 4 828 841	1 – 10, 18, 20, 21, 28, 32 – 35 11 – 17, 19, 23, 29, 30	Novedad y Nivel inventivo
D3	US 4 820 524	22	Novedad y Nivel inventivo

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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 OESPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista, de fecha
28 SET. 2006

CONCEPTO TÉCNICO No. 1457	EXAMINADOR TÉCNICO Código 202007
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