

265266

FORMULARIO ÚNICO DE CORRECCIONES Y MODIFICACIONES

SOLICITUD DE

1

☐

Corrección de error material

☒

Modificación a una solicitud

2

SOLICITANTE

Nombre **McNeil-PPC, Inc**
Dirección **Grandview Road, Skillman, New Jersey 08558, Estados Unidos de América**
Nacionalidad o Domicilio **Skillman, New Jersey, Estados Unidos de América**
Lugar de Constitución **New Jersey, Estados Unidos de América**
Teléfono _____ Fax _____
E-mail _____

IDENTIFICACIÓN

C C ☐ NIT ☐
C E ☐ Otro ☐
Cual _____
Número _____

3

**REPRESENTANTE
O APODERADO**

Nombre **JIMENA ESCOBAR URIBE**
Dirección **Cra 11A No 94-76 (Of 305)**
Teléfono **6 162051/61** Fax **6 161889**
E-mail **tm-patent@escobaruribe.com**

IDENTIFICACIÓN

C C ☒ NIT ☐
C E ☐ Otro ☐
Cual _____
Número **39 779 452 T P 68 228**

4 Número del expediente

02-041.349

5 Descripción de la corrección o modificación solicitada Que se anote.

La adición de **CHRISTOPHER SZYMCAK** como inventor de la solicitud de la referencia, para la cual presento documento de cesión debidamente apostillado.
Sobre el particular, es importante resaltar que de conformidad con las normas legales vigentes, artículo 1 de la Resolución 210 de 2001, expedida por el Superintendente de Industria y Comercio y artículo 2 de la Convención de la Haya, el documento en inglés que se pretenda aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requieren traducción. Por otro lado, la legalización consular y/o diplomática de los documentos expedidos en el extranjero no es necesaria. Por lo tanto, el documento de cesión anexo a este memorial es válidamente presentado en idioma inglés y con la correspondiente Apostilla.

6 Comprobante de pago No 05 - 80.666 Fecha 19 de octubre de 2005

7 Anexos

- ☐ Comprobante de pago de la tasa
- ☐ Poderes, si fuere el caso *Protocolo No 16 485
- ☐ Documento que acredita la existencia y representación legal de las partes, cuando sean personas jurídicas No. 16.485

8

NOMBRE JIMENA ESCOBAR URIBE

FIRMA


C C 39 779 452 de Usaquén T P 68228

2667
2471
287

SUPERINDUSTRIA Y COMERCIO
Radicacion : 00041349 00000006 Folios. 14
Fecha (AMB) 2005-11-04 14 17:44
Tramite 002 PATENTES D 1 REGISTRADO/ 329 COMPLETOS
Dependencia 2020 DIVISION DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT 800176089-2

RECIBO OFICIAL DE CAJA 05 - 80,666
FECHA OCTUBRE 19 DE 2005

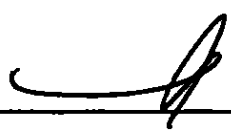
***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No PAGO	FECHA PGO	Vr PAGO
ESCOBAR URIBE ASOCIADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	35418869	19/10/2005	5,754,000 00

***** CONCEPTO *****

CANT	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-03	CAMBIO DE MODALIDAD Y MODIFICA	
		12 MARCAS Y LEHAS COMERCIALES	91,000 00
		TOTAL	\$ 91,000 00

SOM NOVENTA Y UNO MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No _____

APOSTILLE

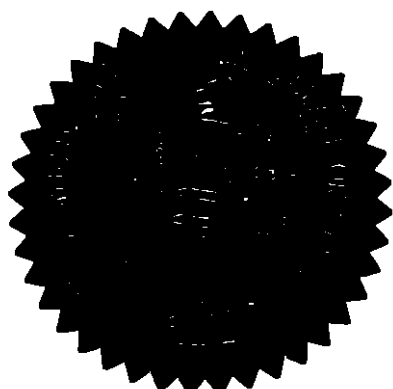
(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

- 1 COUNTRY UNITED STATES OF AMERICA
2 THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY
CHRISTINA A CLICKNER
3 ACTING IN THE CAPACITY OF
NOTARY PUBLIC OF NEW JERSEY
4 BEARS THE SEAL/STAMP OF
CHRISTINA A CLICKNER, NOTARY

CERTIFIED

- 5 AT TRENTON, NEW JERSEY
6 THE 11TH DAY OF OCTOBER 2005
7 BY John E McCormac, CPA, NEW JERSEY TREASURER
8 NO A240803
9 SEAL/STAMP

10 SIGNATURE

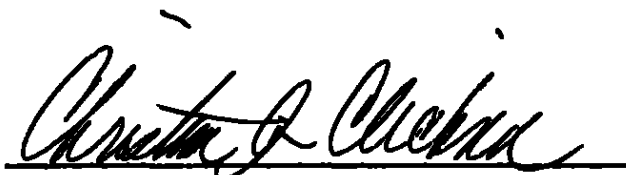


John E McCormac

MCP 303 CO

CERTIFICATION

I hereby certify that I have compared the attached document with the original, and that such said document is a true copy of the original Assignment document as filed in the U S Patent Office in connection with USSN 10/122,999 filed APRIL 12, 2002

A handwritten signature in cursive script, reading "Christina A. Clickner", is written over a horizontal line.

**Christina A Clickner
(Notary Public of New Jersey)
My Commission Expires
March 2, 2010**

A S S I G N M E N T

Serial No 10/122,999
Filed 12 April 2002

WHEREAS, Cynthia Gullian, Walter G Gowan, Jr , Kishor B Parekh, Joseph M Morris, Thomas J Markley, Dennis C Wieand, Gerard P McNally, and Christopher Szymczak, residing at 117 Crestwood Drive, Lansdale, PA 19446, 81 Parkhurst Drive, Westford, MA 01866, 33 Greenwoods Drive, Horsham, PA 19044, 180 Lafayette Road, Coatesville, PA 19320, 111 Green Tree Tavern Road, North Wales, PA 19454, 2650 Possum Hollow Road, Coopersburg, PA 18036, 177 Coldstream Drive, Berwyn, PA 19312, and 79 Colts Gait Road, Marlton, NJ 08053, respectively (hereinafter called "Assignors"), have made certain new and useful inventions or discoveries relating to

DIP COATING COMPOSITIONS CONTAINING CELLULOSE ETHERS

for which on the 12th day of April, 2002 was filed an application for Letters Patent of the United States, and

WHEREAS, McNEIL-PPC, Inc , a corporation of the State of New Jersey, (hereinafter called "Assignee"), is desirous of acquiring Assignors' entire right, title, and interest therein

NOW, THEREFORE, BE IT KNOWN that for and in consideration of the sum of One Dollar and other valuable considerations to them moving, the receipt of which is hereby acknowledged, Assignors have sold, assigned, and transferred, and do hereby sell, assign and transfer unto said Assignee their entire right, title and interest in and to all said inventions and discoveries disclosed in said application whose identification above by serial number and filing date, when available is hereby authorized, and in and to said application, all substitutions, divisions, and continuations thereof, and in and to all Letters Patent, United States and foreign, that may be granted for said inventions and discoveries, and in and to all extensions, renewals, and reissues thereof, the same to be held and enjoyed by said Assignee, its successors and assigns, as fully and entirely as the same would have been held and

enjoyed by Assignors if this Assignment and sale had not been made,

And Assignors hereby authorize and request the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment,

And for the consideration aforesaid, Assignors covenant and agree with said Assignee that he has a full and unencumbered title to the inventions and discoveries above described and hereby assigned, which title they warrant unto said Assignee, its successors and assigns,

And for the consideration aforesaid, Assignors further covenant and agree that they will, whenever requested, but without cost to them promptly communicate to said Assignee or its representatives any facts known to them relating to said inventions and discoveries, testify in any interference or legal proceedings involving said inventions and discoveries, and execute any additional papers that may be necessary to enable said Assignee or its representatives, successors, nominees, or assigns to secure full and complete protection for the said inventions and discoveries or that may be necessary to vest in said Assignee the complete title to the said inventions and discoveries and patents hereby conveyed and to enable it to record said title

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USSN 10/122,999
Filed April 12, 2002

IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 6th day of September 2005

Cynthia M. Gulian (L S)
Cynthia Gulian

STATE OF PA)
COUNTY OF Montgomery) ss

September, 2005, before me, a Notary Public, personally
appeared Cynthia Gulian, who I am satisfied is the person named
in and who executed the foregoing instrument in my presence, and
I having first made known to him/her the contents thereof,
he/she did acknowledge that he/she signed, sealed, and delivered
the same as his/her voluntary act and deed for the uses and
purposes therein expressed

Barbara M. Gilmore
Notary Public

Notarial Seal
Barbara M. Gilmore, Notary Public
Whiteland Twp. 4 - Montgomery County
My Commission - Expires April 15, 2008
Member Pennsylvania Association Of Notaries

USSN 10/122,999
Filed April 12, 2002

22⁸
23

IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 31st day of August 2005

Walter G Gowan Jr (L S)

STATE OF *Massachusetts*) ss
COUNTY OF)

COUNTY OF
Middlesex

BE IT REMEMBERED, That on this 31st day of August, 2005, before me, a Notary Public, personally appeared Walter G Gowan, Jr, who I am satisfied is the person named in and who executed the foregoing instrument in my presence, and I having first made known to him/her the contents thereof, he/she did acknowledge that he/she signed, sealed, and delivered the same as his/her voluntary act and deed for the uses and purposes therein expressed

James J. Murphy - Kurovsk
Notary Public

My Commission ends on
October 23, 2009

USSN 10/122,999
Filed April 12,2002

273 9
274

IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 31st day of August 2005

Kishor B Parekh (L S)
Kishor B Parekh

STATE OF PA)
COUNTY OF Montgomery) SS

BE IT REMEMBERED, That on this 31st day of
August, 2005, before me, a Notary Public, personally
appeared Kishor B Parekh, who I am satisfied is the person
named in and who executed the foregoing instrument in my
presence, and I having first made known to him/her the contents
thereof, he/she did acknowledge that he/she signed, sealed, and
delivered the same as his/her voluntary act and deed for the
uses and purposes therein expressed

Barbara M. Gilmore
Notary Public

Notarial Seal
Barbara M. Gilmore, Notary Public
Whitmarsh Twp., Montgomery County
My Commission Expires April 15, 2008
Member Pennsylvania Association Of Notaries

USSN 10/122,999
Filed April 12, 2002

229 to
275

IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 31st day of August 2005

Joseph M Morris (L S)
Joseph M Morris

STATE OF PA)
COUNTY OF Montgomery) ss

BE IT REMEMBERED, That on this 31st day of August, 2005, before me, a Notary Public, personally appeared Joseph M Morris, who I am satisfied is the person named in and who executed the foregoing instrument in my presence, and I having first made known to him/her the contents thereof, he/she did acknowledge that he/she signed, sealed, and delivered the same as his/her voluntary act and deed for the uses and purposes therein expressed

Barbara M Gilmore
Notary Public

Notarial Seal
Barbara M. Gilmore, Notary Public
Whitmarsh Twp., Montgomery County
My Commission Expires April 15, 2008
Member Pennsylvania Association Of Notaries

USSN 10/122,999
Filed April 12, 2002

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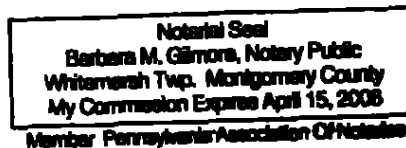
IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 25th day of August 2005

Thomas J. Markley (L S)
Thomas J. Markley

STATE OF PA)
COUNTY OF Montgomery) ss

August BE IT REMEMBERED, That on this 25th day of
2005, before me, a Notary Public, personally
appeared Thomas J. Markley, who I am satisfied is the person
named in and who executed the foregoing instrument in my
presence, and I having first made known to him/her the contents
thereof, he/she did acknowledge that he/she signed, sealed, and
delivered the same as his/her voluntary act and deed for the
uses and purposes therein expressed

Barbara M. Gilmora
Notary Public



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USSN 10/122,999
Filed April 12, 2002

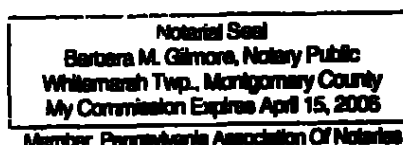
IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 26th day of August 2005

Dennis C. Wieand (L S)
Dennis C. Wieand

STATE OF PA)
COUNTY OF Montgomery) ss

BE IT REMEMBERED,
That on this 26th day of August, 2005, before me, a Notary
Public, personally appeared Dennis C. Wieand, who I am satisfied
is the person named in and who executed the foregoing instrument
in my presence, and I having first made known to him/her the
contents thereof, he/she did acknowledge that he/she signed,
sealed, and delivered the same as his/her voluntary act and deed
for the uses and purposes therein expressed

Barbara M. Gilmore
Notary Public



277-13
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IN TESTIMONY WHEREOF, Assignors have hereunto set
their hands and seals this 6th day of September 2005

Gerard P McNally (L S)
Gerard P McNally

STATE OF PA)
COUNTY OF Montgomery) ss

BE IT REMEMBERED, That on this 6th day of September, 2005, before me, a Notary Public, personally appeared Gerard P. McNally, who I am satisfied is the person named in and who executed the foregoing instrument in my presence, and I having first made known to him/her the contents thereof, he/she did acknowledge that he/she signed, sealed, and delivered the same as his/her voluntary act and deed for the uses and purposes therein expressed

Barbara M. Gilmore
Notary Public

Notarial Seal
Barbara M. Gilmore, Notary Public
Whitemarsh Twp. Montgomery County
My Commission Expires April 16, 2008
Member Pennsylvania Association Of Notaries

USSN 10/122,999
Filed April 12, 2002

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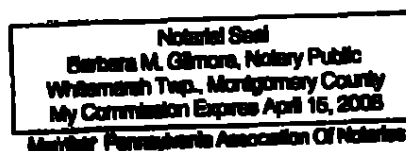
IN TESTIMONY WHEREOF, Assignors have hereunto set their
hands and seals this 29th day of August 2005

Christopher Szymczak (L S)
Christopher Szymczak

STATE OF PA)
COUNTY OF Montgomery) SS

BE IT REMEMBERED, That on this 29th day of
August, 2005, before me, a Notary Public, personally
appeared Christopher Szymczak, who I am satisfied is the person
named in and who executed the foregoing instrument in my
presence, and I having first made known to him/her the contents
thereof, he/she did acknowledge that he/she signed, sealed, and
delivered the same as his/her voluntary act and deed for the
uses and purposes therein expressed

Barbara M. Gilmore
Notary Public



DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No 02-41349

EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION
PCT FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 540,
DE FECHA 31 DE MAYO DE 2004, EL TERMINO HABIL SEÑALADO POR LA
LEY EXPIRA EL 30 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 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 _____

280
281

D1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication
05.08.1998 Bulletin 1998/23

(51) Int Cl⁸ A61K 9/48

(21) Application number 96307888.7

(22) Date of filing 08.11 1996

(84) Designated Contracting States.
DE ES FR GB IT

(30) Priority 01.12.1994 JP 323551/94
16.12.1994 JP 333865/94

(71) Applicant JAPAN ELANCO COMPANY LIMITED
Kita-ku, Osaka (JP)

(72) Inventors
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(74) Representative: Stoner, Gerard Patrick et al
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London WC2B 6HP (GB)

(54) Capsule shell compositions and their use

(57) A capsule shell is formed of a composition comprising 18-28 parts by weight of hydroxypropylmethyl cellulose whose 2% aqueous solution has a viscosity of 2-4-5-4 centistokes at 20°C as a base 0.01-0.1 part by

weight of carrageenan as a gelling agent, and 0.05-0.8 part by weight of a potassium and/or calcium ion as a co-gelling agent. The capsule shell exhibits disintegrating ability equivalent to gelatin shells without losing that ability even under special conditions. In particular a high concentration of calcium ions.

Cápsulas revestidas com
HPMC
carragenina (viscosante)

pins is concentrated to form hard shells around the pins. Other conditions may be the same as used in the manufacture of conventional gelatin shells.

Hard capsules formed of the present compositions are well suited for medical application. They may be also used in other applications such as food.

We find that these capsule shell compositions have good shapability and disintegration ability comparable to conventional gelatin shells even in special conditions where much calcium ion is present. HPMC capsules of the inventive composition will effectively disintegrate in the stomach even when they are administered after drinking milk containing much calcium ions, achieving equivalent performance to conventional gelatin capsules. Then the invention enables to take full advantage of HPMC-base hard capsules.

EXAMPLE

Examples of the invention are given below by way of illustration and not by way of limitation. All percents are by weight.

Example 1 and Comparative Example 1

Potassium chloride was dissolved in pure water at about 75°C. With stirring, κ-carrageenan and a coloring agent (titanium oxide) were added to the solution and dissolved therein. With stirring, hydroxypropylmethyl cellulose (HPMC) was added to the solution and dispersed therein. The solution was cooled to a temperature of 50°C and further agitated for dissolving the HPMC therein. The solution was then allowed to stand for deaeration. In this way, two immersion solutions were obtained as shown in Table 1.

A conventional capsule shell forming apparatus was charged with the immersion solution which was maintained at 52°C. The apparatus was operated in accordance with a conventional dipping technique to prepare No. 2 capsule shells of the shell composition shown in Table 1 having a thickness of 0.1 mm. In this way, two types of capsule shells were obtained.

Table 1

	Example 1	Comparative Example 1
Immersion solution		
HPMC TC-5R		18%
TC-5MW	10%	
TC-5EW	10%	
Viscosity	3.8 cst	6.0 cst
κ-carrageenan	0.08%	0.2%
Potassium chloride	0.11%	0.1%
(potassium ion)	(0.06%)	(0.05%)
Titanium oxide	0.77%	0.62%
Capsule shell		
HPMC	89.83%	89.83%
κ-carrageenan	0.36%	1.12%
Potassium chloride	0.50%	0.56%
(potassium ion)	(0.26%)	(0.29%)
Titanium oxide	3.51%	3.49%
Note: TC-5R, TC-5MW and TC-5EW are trade names of HPMC manufactured by Shin-Etsu Chemical Co., Ltd. TC-5R has a viscosity of 6.0 centistokes, TC-5MW has a viscosity of 4.5 centistokes, and TC-5EW has a viscosity of 3.0 centistokes as measured in 2% aqueous solution at 20°C. The viscosity of Example 1 is that of a 1/1 mixture of TC-5MW and TC-5EW.		

The capsules were filled with 0.3 g of corn starch and immersed in an aqueous solution of 0.1M potassium chloride at 37°C. The opening time was measured by means of a disintegration tester as prescribed in the Pharmacopoeia of Japan. Three measurements were taken and an average was calculated. The results are shown in Table 2. As a reference, a conventional gelatin capsule was similarly measured for opening time with the results shown in Table 2.

United States Patent [19]
Signorino

[11] Patent Number: 5,591,455
[45] Date of Patent: Jan. 7, 1997

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D2

[54] WET POWDER FILM FORMING COMPOSITIONS
[75] Inventor Charles A. Signorino, King of Prussia, Pa.
[73] Assignee: Warner-Jenkinson Company, Inc., St. Louis, Mo.

4,994,285 2/1991 Hsiao et al. 426/104
5,126,145 6/1992 Evenstad et al. 424/465

Primary Examiner—Thurman K. Page
Assistant Examiner—William E. Benston, Jr.
Attorney, Agent, or Firm—Whyte Hirschboeck Dudek S.C.

[21] Appl. No. 382,283
[22] Filed Feb. 1, 1995

Related U.S. Application Data

[60] Division of Ser. No. 73,793, Jul. 27 1993, which is a continuation-in-part of Ser. No. 630,815, Dec. 20, 1990, abandoned.
[51] Int. Cl.⁶ A61K 9/16, A61K 9/50
[52] U.S. Cl. 424/490; 424/489, 424/488, 424/465
[58] Field of Search 424/490, 489, 424/488, 34, 465, 426/104

[56] References Cited
U. S. PATENT DOCUMENTS
4,543,370 9/1985 Porter et al. 424/34

[57] ABSTRACT

An improved wet powder, edible, film-forming composition for use in coating tablets and capsules consists essentially of powdered pigment particles, a film-forming, water soluble or water-dispersible, edible polymer and up to approximately 30% by weight of water. Such compositions are formed by blending the pigment particles and the polymer and applying the water onto the pigment-polymer blend in atomized form. Similar wet powder edible, clear film-forming compositions for use in coating tablets and capsules with a clear coating consist essentially of a film-forming, water soluble or water-dispersible, clear, edible polymer and up to approximately 30% by weight of water and are formed by applying the water onto the polymer in atomized form. The application of water in this manner preconditions the polymer and permits the preparation of smooth stable coating suspensions upon dilution with additional water and without the formation of fish eyes.

14 Claims, No Drawings

Tabletas recubiertas con
HPMC
malto dextrina (viscosante)

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WET POWDER FILM-FORMING COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATION

This is a division of application Ser. No. 08/073,795, filed Jul. 27, 1993 which is a continuation-in-part of application Ser. No. 630,815, filed Dec. 20, 1990.

BACKGROUND OF THE INVENTION

This invention relates to film-forming or film coating compositions for use in the film coating of pharmaceutical tablets and the like and, more particularly, to such compositions in the form of wet powder blends or wet powder, clear, film-forming compositions.

Signorino U.S. Pat. No. 3,981,984 discloses edible concentrated pigment suspension in which pigments are suspended in non-aqueous solvents. Such pigment suspensions are shipped, for example, to pharmaceutical manufacturers who mix them with polymer solutions to form coating suspensions used for coating tablets and the like. Each of the pigment suspensions, polymer solutions and coating suspensions formed therefrom are in a non-aqueous solvent.

Porter et al. U.S. Pat. No. 4,543,370 discloses a dry edible film coating composition for use in pharmaceuticals, confectionery and food which comprises a mixture including pigment particles, polymer particles, a polymer plasticizer such as polyethylene glycol 400 and, advantageously, a surfactant such as dioctyl sodium sulfosuccinate. According to the patentees, such a film coating composition responds to a long standing desire to provide a dry edible film coating composition which can be constituted with solvent by the customer, that eliminates the problem of shipping of pigment dispersions containing aqueous or non-aqueous solvents, and also makes shipping less expensive by eliminating the weight of the solvents. In U.S. Pat. No. 4,543,370 it is stated to be known in the prior art to mix a dry polymer powder with pigment particles and to grind the mixture to obtain a dry polymer-pigment mixture which is then ground into a fine powder mixture. However as further stated in this patent, when this fine polymer-pigment mixture is stirred into water and dispersed, the polymer makes lumps and fish eyes because it agglomerates and the resultant dispersion is not uniform. When this polymer-pigment dispersion is used as a coating dispersion and is coated onto tablets and the like, unless the dispersion is left to solvate for a considerable period of time like overnight, the coating is lumpy and not uniform.

The dry coating compositions of U.S. Pat. No. 4,543,370 are stated to be useful within an hour of being made up and not to require an overnight waiting period as was required by prior art aqueous and non-aqueous systems.

Holmes U.S. Pat. No. 4,636,261 discloses dry mixtures of powdered edible pigment particles and a dispersing agent which prevents agglomeration and facilitates dispersion into solution. The dispersing agent may be the salt of an organic compound containing one to four carboxylic acid groups or a salt of phosphoric acid.

In the preparation of clear film coating compositions for coating aspirin tablets and the like, it has heretofore been the practice to dissolve or disperse a polymer such as hydroxypropylmethyl cellulose in water and then wait for a period of 18 hours or so before applying the resulting polymer solution or dispersion to tablets or the like. Such a waiting

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period has been deemed necessary in order to rid the solution or dispersion of fish eyes and allow water to penetrate into or hydrate the polymer gel particles (fish eyes) which form upon dissolving or dispersing the polymer in water. While pre-conditioned or surface-treated polymers are available, it is necessary to add a base material to such polymers in order to allow the polymers to become hydrated and dissolve or disperse in water.

There remains a need for further improvements in film coating compositions with regard to their ability to disperse color in the coating of tablets, capsules and the like and their usefulness for this purpose upon preparation or within a short time thereafter.

SUMMARY OF THE INVENTION

Among the objects of the present invention may be noted the provision of film-forming compositions useful in coating tablets, capsules and the like which are produced in the form of wet powder blends, the provision of clear film-forming compositions for use in coating tablets and capsules with a clear coating; the provision of such compositions which are capable of forming stable suspensions for coating tablets, capsules or the like upon dilution with additional water; the provision of compositions of this type which can be used for coating tablets and capsules shortly after being combined with additional water and a plasticizer; and the provision of methods of making such film forming compositions. Other objects and features will be in part apparent and in part pointed out hereinafter.

Briefly, the present invention is directed to a wet powder, edible, film-forming composition for use in coating tablets, capsules and the like which consists essentially of powdered pigment particles, a film-forming, water-soluble or water-dispersible, edible polymer and between approximately 1% and approximately 30% by weight of water, the composition being formed by blending the pigment particles and polymer and applying the water onto the pigment-polymer blend in atomized form and the composition being capable of forming a stable suspension upon dilution with additional water. Preferably, the composition also contains a dispersing agent such as an alkali metal or ammonium salt of ethylene diamine tetraacetic acid which lowers the surface tension of water in the composition.

The invention is also directed to a method of making a wet powder, edible, film-forming composition of the type described above for use in coating tablets, capsules and the like which comprises (a) blending powdered pigment particles and a film-forming, water-soluble or water-dispersible edible polymer; and (b) applying water or an aqueous solution of the above-mentioned dispersing agent onto the pigment-polymer blend in atomized form, the composition containing between approximately 1% and approximately 30% by weight of water.

The invention, in another embodiment, is further directed to a wet powder edible, clear, film-forming composition for use in coating tablets, capsules and the like with a clear coating consisting essentially of a clear, film-forming, water-soluble or water-dispersible, edible polymer and between approximately 1% and approximately 30% by weight of water, the compositions being formed by applying water onto the polymer in atomized form and the composition being capable of forming a stable suspension upon dilution with additional water without the formation of fish eyes. The composition of this embodiment of the invention preferably also contains a dispersing agent of the aforementioned type,

and the invention further encompasses a method of making a clear film forming composition of this embodiment.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In accordance with the present invention, it has now been unexpectedly found that useful wet powder, edible, film-forming compositions for coating tablets, capsules and the like may be formulated by blending powdered pigment particles with a film-forming, water-soluble or water-dispersible, edible polymer and applying water onto the pigment-polymer blend in atomized form. When formulated in this manner the resulting film-forming compositions have been found capable of tolerating up to approximately 30% by weight water while yet remaining capable of forming a stable suspension upon dilution with additional water. Also, the film-forming compositions prepared in accordance with the present invention and containing between approximately 1% and approximately 30% by weight of water do not lump up or contain fish eyes and, when combined with additional water and a plasticizer provide a smooth, uniform coating for pharmaceutical tablets, capsules and the like. Optionally, but preferably the film-forming compositions of the invention also contain a dispersing agent constituted by an acid salt which lowers the surface tension of the water in the composition and which in turn lowers the viscosity of the final coating suspension to thereby provide improved and smoother coatings for tablets and the like.

It is believed that the addition or application of water onto the pigment-polymer blend in atomized form in accordance with the invention advantageously preconditions the polymer and avoids clumping or the formation of fish eyes when the compositions of the invention are added to water to form coating suspensions. Thus, by applying the water in atomized form, the water becomes uniformly distributed over or to all polymer particles, the pigment particles adhere to the polymer particles and the polymer is preconditioned so that hydration of the polymer is expedited when the pigment polymer blend is dispersed in water to form a coating suspension. Accordingly the present invention achieves the advantageous preconditioning of the blend of pigment and polymer causing the blend to readily disperse and dissolve in water in forming the desired coating suspension without deleterious lumping or agglomeration. Moreover, through the present invention, it becomes possible to prepare smooth coating suspensions which can be used immediately or within 30 minutes for the coating of tablets or the like.

In the practice of the present invention, powdered pigment particles are first blended or admixed with a film-forming, water-soluble or water-dispersible, edible polymer. Water or an aqueous solution of a dispersing agent which lowers the surface tension of water is then applied onto the pigment-polymer blend in atomized form to produce a film-forming composition containing between approximately 1% and approximately 30% by weight of water. For use as the powdered pigment component of the compositions of the invention, any FDA-approved edible natural or synthetic colorant may be employed. Useful pigments include, but are not limited to, FD&C and D&C dyes, FD&C and D&C lakes, titanium dioxide, iron oxides, talc, alumina, silica and natural colorants. Typically, the powdered pigment particles may be constituted by a combination of a lake and titanium dioxide or iron oxide. The particle size of the powdered pigment particles is not critical, but the finer the particle size, the better the results achieved through the present invention. The particle size of commercially avail-

able pigments known to those in the art renders them satisfactory for use in the compositions of the invention.

In order to be useful in the invention, the film-forming, edible polymer component must be water-soluble or water-dispersible. Useful polymers of this type include methyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, maltodextrin, polydextrose, modified starches (such as "Purity Gum 59" marketed by National Starch) and natural gums such as gum tragacanth, gum acacia and xanthan gums, with hydroxypropylmethyl cellulose being the preferred polymer. Mixtures of such polymers may also be used. It is preferred that the polymer be in powdered form, but the particular particle size of the polymer is not critical in the practice of the invention.

After the powdered pigment and polymer have been blended until uniform, the desired amount of water per se or in the form of an aqueous solution of a dispersing agent is added with intense mixing so that the water or aqueous solution of the dispersing agent is applied to the pigment polymer blend in atomized form. This can be accomplished, for example, by blending the powdered pigment and polymer in a PK Blender or a Littleford FM 130 Blender and adding the water or aqueous solution of dispersing agent with intense mixing by fine atomization into the blender chamber where the powdered pigment and polymer are being mixed. Preferably the water or aqueous solution is added slowly and the resulting water-containing blend or composition is mixed intensely after addition of the water.

It has been found that film-forming compositions prepared in this manner may contain up to approximately 30% by weight of water and yet remain capable of forming a stable suspension useful for coating tablets and the like upon dilution with additional water. It should be noted that where FD&C lakes are employed as pigments, they may contain up to 15% by weight of water and that the polymer component may likewise contain up to 4% to 6% by weight of water. The water added through the practice of this invention is additional water over and above that contained in the pigment and polymer components and, as stated, may range from approximately 1% to 30% by weight, with approximately 2% to 10% by weight being the preferred amount and approximately 5% to 9% by weight being the most preferred amount.

In an optional but highly preferred embodiment, a dispersing agent which lowers the surface tension of water is incorporated into the film-forming compositions of the invention. The dispersing agent is constituted by an acid salt which functions to lower the surface tension of water in the compositions and illustrative acid salts which perform this function include the alkali metal and ammonium salts of ethylene diamine tetracetic acid, nitro triacetic acid, citric acid, phosphoric acid, tartaric acid, glycolic acid, malic acid, lactic acid, acetic acid and benzoic acid. It will be understood that other acid salts which function to lower the surface tension of water in the compositions may also be employed in the practice of the invention. Sodium salts of ethylene diamine tetracetic acid represent the preferred dispersing agents for use in the practice of the invention. The dispersing agent is generally incorporated into the film-forming compositions in the form of aqueous solutions of such acid salts, such aqueous solutions being applied to the pigment-polymer blends as previously described and providing the amount of water to be added to the compositions as well as acting as the vehicle for the application of the dispersing agent to the pigment-polymer blends. Alternatively but less preferably, the dispersing agent may be added in powder form to the pigment-polymer blend with the water

being applied to the resulting blend of the three components in atomized form. The dispersing agent not only lowers the surface tension of the water in the film-forming compositions of the invention but also lowers the viscosity of the coating suspensions prepared from such compositions thereby providing smaller suspension droplets and smoother coatings for tablets and the like. While the invention may be practiced without the addition of a dispersing agent to the film-forming compositions, it has been found that the incorporation of a dispersing agent produces a better color development and quality of coating for tablets and the like.

The film-forming compositions of the invention are shelf-stable for extended periods of time without the use of preservatives and are not prone to settling or other breakdowns. Further, it is believed that such compositions remain free from bacteria formation such as may be normally caused by the solvent in liquid pigment dispersions.

To prepare coating suspensions for use in coating tablets and the like, the film-forming compositions of the invention are added to water and a plasticizer in accordance with conventional practice. The coating suspensions so prepared may be applied immediately to tablets without a waiting period such as overnight as is required with certain prior art systems. Any of the plasticizers known to the art such as polyethylene glycol 400, glycerin, propylene glycol, glycerine triacetate, triethyl citrate, tributyl citrate or diethyl phthalate may be used in formulating coating suspensions from the wet film-forming compositions of the invention.

In another, but less preferred, embodiment of the invention, a plasticizer may be incorporated into the wet film-forming compositions of the invention so that the resulting compositions may be simply added to water in order to form useful coating suspensions for coating tablets and the like.

In preparing the wet powder, edible, film-forming compositions of the invention, the proportions of pigment and polymer employed are not critical. In general where the ratio of pigment to polymer is high, a flat appearing film of lower quality will be obtained whereas with lower ratios of pigment to polymer, a more glossy film results and better film properties will be obtained. For acceptable results, the weight ratio of polymer to pigment should range between 1.5:1 and 3:1 with the ratio of approximately 2.5:1 being preferred where the pigment component is primarily constituted by a lake.

The proportion of dispersing agent incorporated into the film-forming compositions of the invention may vary widely but, in general, may constitute between 0.1 to 5.0% by weight based on the weight of the pigment and polymer components and more preferably between 0.5 to 2.0% by weight.

In another embodiment and in further accordance with the invention, it has also been unexpectedly found that useful wet powder, edible, clear film-forming compositions for coating tablets, capsules and the like with a clear coating may be formulated by applying water onto a film-forming, water-soluble or water-dispersible, edible, clear polymer in atomized form. Here again, when formulated in this manner the resulting clear film-forming compositions have been found capable of tolerating up to approximately 30% by weight water without forming fish eyes while yet remaining capable of forming a stable suspension upon dilution with additional water. Such clear film-forming compositions prepared as described above and containing between approximately 1% and 30% by weight of water do not lump up or contain fish eyes and therefore require no long waiting period or pretreatment of the polymer component before

being used to make coating compositions. When combined with additional water and a plasticizer, such clear, film-forming compositions yield a smooth, uniform coating composition for coating pharmaceutical tablets, capsules and the like with a clear coating. When a plasticizer is incorporated, water is first applied onto the polymer in atomized form following which the plasticizer is sprayed onto the resulting composition. Through this embodiment of the invention, it becomes possible to prepare smooth, clear coating suspensions which can be used immediately or within 30 minutes for providing tablets, capsules or the like with a clear coating. In this embodiment of the invention, it is also optional, but preferable, for the clear, film-forming compositions to contain a dispersing agent constituted by an acid salt which lowers the surface tension of the water in the composition. Any of the dispersing agents enumerated above may be used in this embodiment of the invention.

In forming clear film-forming compositions as above described, it is believed that the application of water onto the polymer advantageously preconditions the polymer as in the case of the pigment-polymer blend described above and avoids clumping or the formation of fish eyes either upon application of the water or when the resulting clear, film-forming compositions of the invention are added to water to form coating suspensions. Upon the application of water to a clear polymer as previously described, granules or an agglomeration of polymer particles are formed which unexpectedly go into solution readily in contrast to the addition of a polymer per se to water which tends to clump or form fish eyes. In forming clear film-forming compositions of the invention in accordance with this additional embodiment, the same film-forming, water-soluble or water-dispersible, edible polymers, dispersing agents and plasticizers disclosed above may be employed, but the resulting compositions are clear because they contain no pigment component. Also, such clear, film-forming compositions can be prepared using a PK Blender or a Littleford FM 130 Blender which insure that the water is applied to the polymer in atomized form. The water may also be applied in atomized form by means of an aqueous solution of the dispersing agent where the latter is optionally but preferably incorporated into the film-forming compositions.

The following examples illustrate the practice of the invention.

EXAMPLE 1

The following ingredients were charged to a Littleford FM 130 blender:

Hydroxypropylmethyl cellulose	43 lb.
Titanium dioxide	26 lb.
FD&C Yellow 6 Low dye lake	1 lb.

The ingredients were blended for two minutes to form a pigment-polymer blend. 3.5 lb. of a 10% aqueous sodium citrate solution was sprayed onto the pigment-polymer blend with mixing in approximately 2.5 minutes and then mixed for 1 minute after addition of the sodium citrate solution was complete. This effected application of the sodium citrate solution onto the pigment-polymer blend in atomized form. A dustless, free-flowing powdered film-forming composition was produced.

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EXAMPLE 2

The following ingredients were charged to a Littleford W-10 mixer

Hydroxypropylmethyl cellulose	1.36 kg.
Titanium dioxide	0.35 kg.
FD&C Yellow 5 High dye lake	0.20 kg.
FD&C Yellow 6 High dye lake	0.03 kg.

The ingredients were mixed for three minutes to form a pigment-polymer blend. 60 grams of a 10% aqueous solution of the tetrasodium salt of ethylene diamine tetraacetic acid was then sprayed onto the pigment-polymer blend in one minute, with mixing continued for one minute after the addition of the 10% solution was complete. A dustless, free-flowing powder was produced.

EXAMPLE 3

The following ingredients were charged to a PK Blender Model LBC-2P

Hydroxypropylmethyl cellulose	400 g.
Titanium dioxide	100 g.
FD&C Yellow 6 High dye lake	100 g.

The ingredients were mixed for four minutes to form a pigment-polymer blend. 60 grams of water was then sprayed onto the pigment-polymer blend in two minutes, with mixing continued for one minute after the addition of the water was complete. A dustless, free-flowing powder was produced.

EXAMPLE 4

Example 3 was repeated using 60 grams of a 10% aqueous solution of the tetrasodium salt of ethylene diamine tetraacetic acid in place of water. A dustless, free-flowing powder was produced.

EXAMPLE 5

Example 3 was repeated using 60 grams of a 10% aqueous solution of sodium citrate in place of water. A dustless, free-flowing powder was produced.

EXAMPLE 6

Example 3 was repeated using 30 grams of a 10% aqueous solution of sodium dibasic phosphate (Na_2HPO_4) in place of water. A dustless, free-flowing powder was produced.

EXAMPLE 7

Example 3 was repeated using FD&C Red 40 in place of FD&C Yellow 6 High dye lake. A dustless, free-flowing powder was produced.

EXAMPLE 8

Example 3 was repeated using FD&C Red 40 in place of FD&C Yellow 6 High dye lake and 30 grams of a 10% aqueous solution of the trisodium salt of ethylene diamine tetraacetic acid in place of water. A dustless, free-flowing powder was produced.

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EXAMPLE 9

A coating suspension was prepared as follows. 87.5 grams of water and 1.5 grams of polyethylene glycol 400 were charged to a beaker. While stirring the beaker contents vigorously, 11 grams of the powder produced in Example 4 was added to the beaker. The powder readily dispersed and the suspension which formed thickened and became very smooth in 15 minutes.

The resulting coating suspension was applied immediately to tablets in a 4" Wurster Column, and a smooth glossy coating on the tablets was achieved in 15 minutes.

EXAMPLE 10

The following ingredients were charged to a PK Blender Model LBC-2P

Hydroxypropylmethyl cellulose	360 g.
Makrin M-100 (Maleic anhydride)	240 g.

The above polymer ingredients should preferably be distributed equally in each shell of the blender and should be 1/4 to 3/4 the way up the intensifier bar of the blender. The blender was closed and mixing of the dry blend was carried out for 4 to 5 minutes with both the shell and intensifier bar mixing being used. After the polymer ingredients were thus blended, mixing with both the shell and intensifier bar was continued and the liquid feed pump was turned on. 38 grams of a 10% aqueous solution of sodium citrate was fed onto the polymer blend in atomized form followed by the addition of 48 grams of polyethylene glycol 400 as a plasticizer. After the addition of the sodium citrate solution and plasticizer, the liquid feed pump was allowed to run for 1 minute to clear the lines. After the liquid feed pump was shut off, the shell and intensifier bar were allowed to mix for 30 seconds and the blender was shut off. A dustless, free-flowing powder was produced.

EXAMPLE 11

The composition of Example 10 was used to make a coating solution. 863.2 grams of water were added to a container equipped with a variable speed mixer. The mixer was started and once a vortex was formed, 136.8 grams of the composition of Example 10 was added in a steady and consistent manner. The speed of the mixer was increased as the solution became more viscous, with the composition being added to the center of the vortex for best mixing. After the complete addition of the Example 10 composition, the speed of the mixer was reduced to reduce aeration of the solution. The sides of the container were scraped to remove any clumps which were added to the center of the solution. Mixing was continued for 30 minutes to produce a smooth, clear coating solution.

EXAMPLE 12

The clear coating solution of Example 11 was used to coat tablets by column or pan coating. The coating solution of Example 11 was charged to the liquid feed system and the tablets to be coated were charged to the coating equipment. The tablets were warmed and the coating solution was sprayed onto the tablets. The resulting tablets had a smooth, clear, glossy coating.

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EXAMPLE 13

The procedure of Example 10 was generally followed to produce a wet powder edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	68.2
Hydroxypropyl cellulose	22.8
Water	9.0

A dustless, free-flowing powder was produced.

EXAMPLE 14

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	94.6
Sodium citrate	0.4
Water	5.0

A dustless, free-flowing powder was produced.

EXAMPLE 15

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition

Component	Wt. %
Hydroxypropylmethyl cellulose	91.5
Sodium citrate	0.4
Water	8.1

EXAMPLE 16

A dustless, free-flowing powder was produced.

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	84.0
Sodium citrate	1.0
Talc	1.0
Glycerin triacetate	5.0
Water	5.0

A dustless, free-flowing powder was produced.

EXAMPLE 17

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	87.70
Sodium citrate	0.14
Talc	3.90

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-continued

Component	Wt. %
Glycerin triacetate	4.30
Water	3.90

A dustless, free-flowing powder was produced.

EXAMPLE 18

The procedure of Example 10 was generally followed to produce a wet powder edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	90.3
Tetrasodium ethylene diamine tartrate	0.5
Polyethylene glycol	4.5
Water	4.7

A dustless, free-flowing powder was produced.

EXAMPLE 19

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	85.4
Tetrasodium ethylene diamine tartrate	0.5
Polyethylene glycol	4.3
Water	4.6

A dustless, free-flowing powder was produced.

EXAMPLE 20

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	91.5
Talcyl citrate	4.6
Water	3.8

A dustless, free-flowing powder was produced.

EXAMPLE 21

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	84.30
Sodium citrate	0.33
Glycerin triacetate	8.30
Talc	3.50
Water	3.20

A dustless, free-flowing powder was produced.

11 EXAMPLE 22

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	84.50
Sodium citrate	0.35
Glycerin triacetate	8.00
Talc	4.00
Water	3.20

A dustless, free-flowing powder was produced.

EXAMPLE 23

The procedure of Example 10 was generally followed to produce a wet powder, edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	85.50
Sodium citrate	0.35
Glycerin triacetate	6.00
Talc	5.00
Water	3.20

A dustless, free-flowing powder was produced.

EXAMPLE 24

The procedure of Example 10 was generally followed to produce a wet powder edible, clear, film-forming composition having the following composition.

Component	Wt. %
Hydroxypropylmethyl cellulose	78.70
Sodium citrate	0.55
Polyvinyl pyrrolidone	15.70
Water	5.00

A dustless, free-flowing powder was produced.

EXAMPLE 25

The procedure of Example 10 was generally followed to produce a wet powder edible, clear, film-forming composition having the following composition

Component	Wt. %
Hydroxypropylmethyl cellulose	90.20
Tetrasodium ethylene diamine tartrate	0.55
Polyethylene glycol	4.50
Water	4.70

A dustless, free-flowing powder was produced.

EXAMPLE 26

The procedure of Example 10 was generally followed to produce a wet powder edible, clear, film-forming composition having the following composition

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Component	Wt. %
Hydroxypropylmethyl cellulose	93.0
Water	5.0

A dustless, free-flowing powder was produced.

EXAMPLE 27

The procedure of Example 10 was generally followed to produce a wet powder edible, clear, film-forming composition having the following composition

Component	Wt. %
Hydroxypropylmethyl cellulose	90.0
Sodium citrate	0.4
Polyethylene glycol	6.0
Water	3.6

A dustless, free-flowing powder was produced.

EXAMPLE 28

The procedure of Example 10 was generally followed to produce a wet powder edible, clear film-forming composition having the following composition

Component	Wt. %
Hydroxypropylmethyl cellulose	45.75
Modified starch ("Furby Gum 39" National Starch)	45.75
Sodium citrate	0.50
Water	8.00

A dustless, free-flowing powder was produced.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

As various changes could be made in the above methods and products without departing from the scope of the invention, it is intended that all matter contained in the above description shall be interpreted as illustrative and not in a limiting sense.

What is claimed is

1 A wet powder, edible, clear, film-forming composition for use in coating tablets and capsules with a clear coating comprising a clear film-forming, water soluble or water-dispersible, edible polymer and between approximately 1% and approximately 30% by weight of water, said composition being formed by applying water onto said polymer in atomized form and said composition being capable of forming a stable suspension upon dilution with additional water without the formation of fish eyes.

2 The wet powder, edible, clear, film-forming composition as set forth in claim 1 wherein said polymer is selected from the group consisting of methyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, maltodextrin, polydextrane, modified starches and a natural gum selected from the group consisting of gum tragacanth, gum acacia and a xanthan gum.

3 The wet powder, edible, clear film-forming composition as set forth in claim 1 wherein said polymer is hydroxypropylmethyl cellulose.

4 The wet powder, edible, clear, film-forming composition

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tion as set forth in claim 1 wherein said composition contains from approximately 2% to 10% by weight of water.

5. The wet powder, edible, clear, film-forming composition as set forth in claim 1 wherein said composition contains from approximately 5% to 9% by weight of water.

6. The wet powder, edible, clear, film-forming composition as set forth in claim 1 wherein said composition additionally includes a plasticizer.

7. A wet powder, edible, clear film-forming composition for use in coating tablets and capsules with a clear coating comprising a clear film forming, water soluble or water-dispersible, edible polymer, between approximately 1% and approximately 30% by weight of water, and a dispersing agent constituted by an acid salt which lowers the surface tension of water in the composition, said composition being formed by applying an aqueous solution of said dispersing agent onto said polymer in atomized form and said composition being capable of forming a stable suspension upon dilution with additional water without the formation of fish eyes.

8. A wet powder, edible, clear, film-forming composition as set forth in claim 7 wherein said acid salt is selected from the group consisting of the alkali metal and ammonium salts of ethylene diamine tetraacetic acid, nitrilo triacetic acid, citric acid, phosphonic acid, tartaric acid, glycolic acid, malic acid, lactic acid, acetic acid and benzoic acid.

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9. The wet powder, edible, clear film-forming composition as set forth in claim 7 wherein said acid salt is an alkali metal or ammonium salt of ethylene diamine tetraacetic acid.

10. The wet powder, edible, clear, film-forming composition as set forth in claim 7 wherein said polymer is selected from the group consisting of methyl cellulose, hydroxypropylmethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, maltodextrin, polydextrose, modified starches and a natural gum selected from the group consisting of gum tragacanth, gum acacia and a xanthan gum.

11. The wet powder, edible, clear, film-forming composition as set forth in claim 7 wherein said polymer is hydroxypropylmethyl cellulose.

12. The wet powder, edible, clear, film-forming composition as set forth in claim 7 wherein said composition contains from approximately 2% to 10% by weight of water.

13. The wet powder, edible, clear, film-forming composition as set forth in claim 7 wherein said composition contains from approximately 5% to 9% by weight of water.

14. The wet powder, edible, clear film-forming composition as set forth in claim 7 wherein said composition additionally includes a plasticizer

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

2020
 Bogotá, D C , Septiembre 7 de 2006

Abogada
JIMENA ESCOBAR URIBE

ASUNTO	Radicación No	02 041 349
	Trámite	002
	Evento	001
	Actuación	430
	Oficio No	000 - 10448
	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 éteres de celulosa"

1 Documentos estudiados

Para el presente estudio se tuvieron en cuenta el capítulo descriptivo comprendido en los folios 8 - 70 y el capítulo reivindicativo de los folios 71 - 80 de la solicitud

2 Objeto de la Invención

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

Las reivindicaciones 1 - 9, 21 - 23, 26, 31, 34, 35, 38 se refieren a una composición para cubrir un sustrato por inmersión, formada por

- HPMC
- Espesante (goma xantano, carrageno ó sus mezclas) y
- Opcionalmente plastificante (PEG, glicena, sorbitol, 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)
- Colorante (azo, quinoftalona, trifenilmetano, xantano, indigoide, óxido de hierro, dióxido de titanio, naturales ó mezclas)

Las reivindicaciones 10 - 20, 25, 32, 36, 39 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

Las reivindicaciones 24, 33, 37, 40 se refieren al uso

Las reivindicaciones 27 - 30 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 HPMC y Espesante (goma xantano, carrageno 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 y US 10 122 999 de Abril 12 de 2002 con respecto a las cuales la fecha de presentación de la actual solicitud cumple el plazo máximo permitido

3 Usos

El artículo 21 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *"Los productos o procedimientos ya patentados, comprendidos en el estado de la técnica, de conformidad con el artículo 16 de la presente Decisión, no serán objeto de nueva patente, por el simple hecho de atribuirse un uso distinto al originalmente comprendido por la patente inicial"*

El artículo 14 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *"Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial"*

El Artículo 19 de la Decisión 486 de la Comisión de la Comunidad Andina establece que *"Se considerará que una invención es susceptible de aplicación industrial, cuando su objeto pueda ser producido o utilizado en cualquier tipo de industria, entendiéndose por industria la referencia a cualquier actividad productiva, incluidos los servicios "*

Las reivindicaciones reivindicaciones 24, 33, 37, 40 se refieren al uso

Se aclara que, de acuerdo con el Art 14, no se puede otorgar patente a usos porque estos no son un producto ni un procedimiento tecnológico

De otro lado, de acuerdo con el Art 19, se considera que los usos no tienen aplicación industrial porque no se refiere a un tipo de producción ó utilización en ningún tipo de industria

4 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 las reivindicaciones 27 - 30 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

5 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 - 9, que se refieren a una composición para cubrir un sustrato, salta a las 21 - 23 y luego a las 26, 31, 34, 35, 38. Continúa con las reivindicaciones 10 - 20, que se refieren a una forma de dosificación y luego salta a las reivindicaciones 25, 32, 36, 39. Como se observa, no hay una secuencia clara en la forma en que se presenta el capítulo reivindicatorio

6 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	EP 0 714 656	Capsule shell compositions and their use	Jun 06, 1996
D2	US 5 591 455	Wet powder film-forming compositions	Ene 07, 1997

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 – 9, 21 – 23, 26, 31, 34, 35, 38 se refieren a una composición para cubrir un sustrato por inmersión, formada por

- HPMC
- Espesante (goma xantano, carrageno ó sus mezclas) y
- Opcionalmente plastificante (PEG, glicerina, sorbitol, 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)
- Colorante (azo, quinofalona, trifenilmetano, xantano, indigoide, óxido de hierro, dióxido de titanio, naturales ó mezclas)

Las reivindicaciones 10 – 20, 25, 32, 36, 39 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

D1 enseña una composición para cubrir un sustrato, formada por HPMC y Espesante (gomas)

D2 enseña (ver columnas 4, 5, 8, 12, 13) una composición para cubrir un sustrato, formada por HPMC, espesante (gomas naturales), plastificante y colorante

Se observa que los elementos característicos de las composiciones reivindicadas, es decir HPMC y Espesante (gomas), ya eran conocidos en D1 y D2, por lo cual no pueden considerarse nuevas

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 – 9, 21 – 23, 26, 31, 34, 35, 38 se refieren a una composición para cubrir un sustrato por inmersión, formada por

- HPMC
- Espesante (goma xantano, carrageno ó sus mezclas) y
- Opcionalmente plastificante (PEG, glicerina, sorbitol, citrato de tributilo, sebacato de dibutilo, aceites vegetales, tensioactivos, propilenglicol, mono-, di- ó tri- acetato de glicerol, gommas naturales, aceite de castor y sus mezclas)
- Colorante (azo, quinoftalona, trifenilmetano, xantano, indigoide, óxido de hierro, dióxido de titanio, naturales ó mezclas)

Las reivindicaciones 10 – 20, 25, 32, 36, 39 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

D1 enseña una composición para cubrir un sustrato, formada por HPMC y Espesante (gomas)

D2 enseña (ver columnas 4, 5, 8, 12, 13) una composición para cubrir un sustrato, formada por HPMC, espesante (gomas naturales), plastificante y colorante

Se observa que

- (a) debido a que los compuestos HPMC y espesantes (gomas), 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,
- (b) las reivindicaciones de esta solicitud no mencionan una característica que conceda un efecto diferente o especial los compuestos HPMC y espesantes (gomas), ni a las composiciones de recubrimiento, que pueda considerarse como un aporte a la técnica, así que son obvios para una persona versada en la materia,
- (c) el problema planteado en esta solicitud que era la necesidad de un recubrimiento con resistencia, plasticidad, dureza, espesor adecuados que se adhirieran 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 HPMC y Espesante (goma xantano, carrageno ó sus mezclas), es decir de la misma manera como se resolvía en las anterioridades,

- (d) el resultado obtenido es decir composición para cubrir un sustrato por inmersión, formada por HPMC y Espesante (goma xantano, carrageno ó sus mezclas) no es inesperado
- (e) no parece haberse superado un prejuicio técnico anterior, con la composición para cubrir un sustrato por inmersión, formada por HPMC y Espesante (goma xantano, carrageno 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	EP 0 714 656	1 - 9, 21 - 23, 26, 31, 34 35 38 10 - 20, 25, 32, 36, 39	Novedad y Nivel inventivo
D2	US 5 591 455	1 - 9, 21 - 23, 26, 31, 34, 35, 38 10 - 20, 25, 32, 36, 39	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 Única 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

14 SET 2006

CONCEPTO TÉCNICO No. 1456	EXAMINADOR TÉCNICO Código 202007
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