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ESCOBAR - URIBE ASOCIADOS

A B O G A D O S

Carrera 11A No. 94-76 Of. 305 - P.O. Box 94948, Bogotá, Colombia, S.A.
Tels.: (571) 6162051 - 6162061 - 6161859 - 6161869
Fax: (571) 6161889

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

Re: Expediente No. 03.065.794
Solicitud de Patente en 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., solicitante de la patente de la referencia, anexo al presente memorial los siguientes documentos:

1. Anexo al presente memorial el documento de cesión debidamente legalizado mediante Apostilla, suscrito por el inventor a favor de mi mandante.

   A este respecto y de conformidad con las normas legales vigentes, artículo 1 de la Resolución 210 de 2001, expedida por el Superintendente de Industria y Comercio, los documentos en inglés que se pretendan aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requieren traducción. Por lo tanto, el documento de cesión anexo a este memorial es válidamente presentado en idioma inglés.

2. Copia certificada de la solicitud de Patente Número 10/211,139 presentada en los Estados Unidos de América el día 02 de agosto de 2002, con la debida traducción de lo pertinente, incluyendo el capítulo reivindicatorio.

   A este mismo respecto, debe tenerse en cuenta que en la primera página de la copia en mención la Oficina de Patentes correspondiente certificó la fecha de presentación de esa solicitud, cumpliéndose de esta forma todos y cada uno de los requisitos establecidos en el inciso segundo del artículo 10 de la Decisión 486 de la Comisión de la Comunidad Andina.

Señor Superintendente,

JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
T.P. 68228

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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

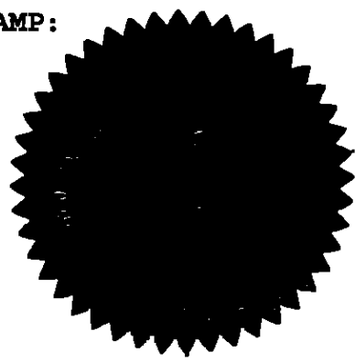
5. AT TRENTON, NEW JERSEY

6. THE 8TH DAY OF AUGUST 2003

7. BY: John E McCormac, CPA, NEW JERSEY TREASURER

8. NO. A178723

9. SEAL/STAMP:



10. SIGNATURE

MCP 324 COL(L)

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 and recorded in the U.S. Patent Office in connection with USSN 10/211,139 filed AUGUST 2, 2002.

Christina A. Clickner
(Notary Public of New Jersey)
My Commission Expires:
March 2, 2005

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UNITED STATES PATENT AND TRADEMARK OFFICE

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JAN 30 2003

MCP 324

JANUARY 24, 2003

PTAS

J&J PAT. DKT. SECTION

Commissioner for Trademarks
Arlington, VA 22202-3513
www.uspto.gov

JOHNSON & JOHNSON
PHILIPS S. JOHNSON, ESQ.
CHIEF PATENT COUNSEL
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NEW BRUNSWICK, NJ 08933-7003

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UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

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PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 10/08/2002

REEL/FRAME: 013378/0112
NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
KAMATH, SATISH

DOC DATE: 08/16/2002

ASSIGNEE:
MCNEIL-PPC, INC.
GRANDVIEW ROAD
SKILLMAN, NEW JERSEY 08558

SERIAL NUMBER: 10211139

FILING DATE: 08/02/2002

PATENT NUMBER:

ISSUE DATE:

SHARON LATIMER, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

CORDATI PAT 10-17-2002

10/8/02

Commissioner of Patent and Trademarks: 102252292

Please record the attached original documents or copy thereof:

1. Name of conveying party(ies):	2. Name and address of receiving party(ies):
Satish Kamath Additional name(s) of conveying party(ies) attached? __ Yes ✓ No	Name: McNEIL-PPC, Inc. Street Address: Grandview Road City: Skillman State: NJ Zip: 08558 Additional name(s) & address(es) attached? __ Yes ✓ No
3. Nature of conveyance: ✓ Assignment __ Merger __ Security Agreement __ Change of Name __ Other Execution Date: August 16, 2002	

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s) 10/211,139 B. Patent No.(s)

Additional numbers attached? __ Yes ✓ No

5. Name and address of party to whom correspondence concerning document should be mailed:	6. Total number of applications & patents involved: 1
Philip S. Johnson, Esq. Chief Patent Counsel Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003	7. Total fee (37 CFR 3.41) ..... $40.00 ✓ Authorized to be charged to Deposit Account 8. Deposit Account Number: 10-0750/MCP-324/MGM

9. Statement and signature

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Michele G. Mangini — Signature — October 2, 2002

Name of Person Signing — Signature — Date

Total number of pages including cover sheet, attachments, and document: 3

Mail documents to be recorded with required cover sheet information to:

Box Assignments
Commissioner of Patent and Trademarks
Washington, D.C. 20231

10/16/2002 TBIAZ1 00000235 100750 10211139
01 FC:8021 40.00 CH

OFFICE OF PETITIONS RECORDS
2002 OCT -8 AM 10 43
FINANCE SECTION

67/6
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DOCKET NO. MCP-324
Sole Inventor

A S S I G N M E N T

Serial No. 10/211,139
Filed August 2, 2002

WHEREAS, Satish Kamath, residing at 202 Windinghill Drive, Hackettstown, NJ 07840 (hereinafter called "Assignor"), has made certain new and useful inventions or discoveries relating to

POLYACRYLIC FILM FORMING COMPOSITIONS

for which he has on the 2nd day of August, 2002 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 the 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 him moving, the receipt of which is hereby acknowledged, Assignor has sold, assigned, and transferred, and does hereby sell, assign, and transfer unto said Assignee the 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 Assignor if this Assignment and sale had not been made;

And Assignor hereby authorizes and requests the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment;

And for the consideration aforesaid, Assignor covenants and agrees with said Assignee that he has a full and unencumbered title to the inventions and discoveries above described and hereby assigned, which title he warrants unto said Assignee, its successors and assigns;

And for the consideration aforesaid, Assignor further covenants and agrees that he will, whenever requested, but without cost to him promptly communicate to said Assignee or its representatives any facts known to him 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.

IN TESTIMONY WHEREOF, Assignor has hereunto set his hand and seal this day of , 2002.

_____(L.S.)
Satish Kamath

STATE OF New Jersey)
) ss.
COUNTY OF Morris)

BE IT REMEMBERED, That on this 16th day of August, 2002, before me, a Notary Public, personally appeared Satish Kamath, 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.

_____
Notary Public

CATHERINE KLUCHARITS
Notary Public
Commission Expires 08-13-2003

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BOGOTA D.C. AGOSTO 20, 2003

TRADUCCIÓN POR TRADUCTOR OFICIAL FOTOCOPIA CERTIFICADO

ESTADOS UNIDOS DE AMERICA

A QUIEN CONOZCA DE ESTE DOCUMENTO

DEPARTAMENTO DE COMERCIO DE ESTADOS UNIDOS

Oficina de Patentes y Marca Registrada

Julio 31, 2003

CON EL PRESENTE SE CERTIFICA QUE EN DOCUMENTO ANEXO AQUÍ ES FIEL COPIA DE LOS REGISTROS DE LA OFICINA DE PATENTES Y MARCA REGISTRADA DE ESOS DOCUMENTOS DE LA SOLICITUD DE PATENTE IDENTIFICADA ADELANTE QUE CUMPLIERON CON LOS REQUERIMIENTOS PARA OTORGARLES UNA FECHA DE RADICACIÓN BAJO 35 USC 111.

NUMERO DE SOLICITUD: 10/211,139
FECHA DE RADICACIÓN: AGOSTO 02, 2002

Por Autoridad de
COMISIONADO DE PATENTES Y MARCAS REGISTRADAS

(HAY FIRMA)
L. EDELEN
Oficial Certificador

FIDEL ANTONIO MURCIA MURCIA
Traductor e Interprete Oficial
Resolución Nr. 488/94 Ministerio de Justicia

TRADUCTOR E INTERPRETE OFICIAL RESOLUCION 488/94 MINJUSTICIA FIDEL ANTONIO MURCIA MURCIA

NOVEDAD DE LA INVENCION

REIVINDICACIONES

1.- Una composición formadora de película que comprende, en base al peso total de sólidos secos de la composición: a) aproximadamente de 10 por ciento a 70 por ciento de un formador de película comprendido de un polímero o copolímero de ácido acrílico o un derivado del mismo, o una mezcla del polímero o copolímero de ácido acrílico o un derivado del mismo; b) aproximadamente de 2 por ciento a 20 por ciento de un plastificante primario comprendido de un parabeno; y c) aproximadamente de 1 por ciento a 50 por ciento de un plastificante secundario seleccionado del grupo que consiste de polivinilpirrolidona, polietilenglicol 300, polietilenglicol 400, sales farmacéuticamente aceptables de los mismos y sus mezclas; en donde la composición posee un lustre de superficie de por lo menos 150 cuando se aplica por recubrimiento de inmersión a un substrato.

2.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque el formador de película se selecciona del grupo que consiste de: a) un polímero o copolímero de ácido metacrílico o un derivado del mismo; y b) mezclas del polímero o copolímero de ácido metacrílico o su derivado.

3.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque el formador de película es copolímero de metacrilato de amonio.

4.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque el formador de película se selecciona del grupo que consiste de: a) poli(acrilato de etilo, metacrilato de metilo, cloruro de trimetilamonioetilo metacrilato) en una relación en peso de 1:2:0.1; b) poli(ácido metacrílico, metacrilato de metilo) en una relación en peso de 1:2; c) poli(ácido metacrílico, metacrilato de metilo) en una relación en peso de 1:1; d) copolímeros de los mismos; y e) mezclas de los mismos.

5.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque el formador de película se selecciona del grupo que consiste de: a) poli(acrilato de etilo, metacrilato de metilo, cloruro de trimetilamonioetilo metacrilato); b) poli(ácido metacrílico, acrilato de etilo); c) poli(acrilato de etilo, metacrilato de metilo); d) poli(acrilato de etilo, metacrilato de metilo)cloruro de trimetilamonioetilo metacrilato); e) copolímeros de los mismos; y f) mezclas de los mismos.

6.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque el parabeno se selecciona del grupo que consiste de metilparabeno, etilparabeno, propilparabeno, butilparabeno, sales farmacéuticamente aceptables de los mismos, y mezclas de los mismos.

7.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque el plastificante secundario es polivinilpirrolidona.

8.- La composición formadora de película de conformidad con la

reivindicación 1, caracterizada además porque está sustancialmente libre de gelatina.

9.- La composición de conformidad con la reivindicación 1, caracterizada además porque comprende, en base al peso seco total de la composición, aproximadamente de 0 por ciento a 14 por ciento de un agente colorante.

10.- La composición de conformidad con la reivindicación 9, caracterizada además porque el agente colorante se selecciona del grupo que consiste de colorantes azo, colorantes de quinoftalona, colorantes de trifenilmetano, colorantes de xanteno, colorantes indigoides, óxidos de fierro, hidróxidos de fierro, dióxido de titanio, colorantes naturales, y mezclas de los mismos.

11.- Un producto que comprende un recubrimiento exterior, dicho recubrimiento exterior estando comprendido de la composición que se reclama en la reivindicación 1.

12.- Una forma de dosis farmacéutica que comprende un recubrimiento exterior, dicho recubrimiento exterior estando comprendido de la composición que se reclama en la reivindicación 1.

13.- La forma de dosis farmacéutica de conformidad con la reivindicación 12, caracterizada además porque comprende una pluralidad de recubrimientos exteriores, en donde por lo menos una primera porción de la forma de dosis está comprendida de un primer recubrimiento exterior, y por lo menos una segunda porción de la forma de dosis está comprendida de un

segundo recubrimiento exterior.

14.- La forma de dosis farmacéutica de conformidad con la reivindicación 13, caracterizada además porque el segundo recubrimiento exterior es visualmente distinto del primer recubrimiento exterior.

15.- Una forma de dosis farmacéutica que comprende un núcleo, una subcapa de recubrimiento que cubre sustancialmente dicho núcleo, y un recubrimiento exterior que cubre sustancialmente dicha subcapa, en donde el recubrimiento exterior está comprendido de la composición que se reclama en la reivindicación 1.

16.- La forma de dosis recubierta de conformidad con la reivindicación 15, caracterizada además porque la subcapa de recubrimiento se selecciona del grupo que consiste de éteres de celulosa, plastificantes, policarbohidratos, pigmentos, opacantes y mezclas de los mismos.

17.- Una tableta recubierta por inmersión con la composición formadora de película que se reclama en la reivindicación 1.

18.- La forma de dosis farmacéutica de conformidad con la reivindicación 12, caracterizada además porque comprende una cantidad efectiva de un ingrediente farmacéutico activo, en donde dicha forma de dosis cumple con los requerimientos de disolución de la USP para formas de liberación inmediata de dicho ingrediente farmacéutico activo.

19.- Una dispersión comprendida de la composición que se reclama en la reivindicación 1 y un solvente.

20.- La dispersión de conformidad con la reivindicación 19,

caracterizada además porque está comprendida, en base al peso total de la dispersión: a) aproximadamente de 10 por ciento a 70 por ciento de un formador de película comprendido de un polímero o copolímero de ácido acrílico o un derivado del mismo, o mezclas de un polímero o copolímero de ácido acrílico o derivados del mismo; b) aproximadamente de 1 por ciento a 40 por ciento de un plastificante primario comprendido de un parabeno; c) aproximadamente de 5 por ciento a 20 por ciento de un plastificante secundario seleccionado del grupo que consiste de polivinilpirrolidona, polietilenglicol 300, polietilenglicol 400, sales farmacéuticamente aceptables de los mismos y sus mezclas; y d) aproximadamente de 5 por ciento a 30 por ciento de agua; en donde la composición posee un lustre de superficie de por lo menos 150 cuando se aplica por recubrimiento de inmersión a un substrato.

21.- Un método para preparar tabletas recubiertas, que comprende recubrir por inmersión tabletas con la dispersión acuosa que se reclama en la reivindicación 20 bajo condiciones suficientes.

22.- Una forma de dosis farmacéutica que comprende un núcleo y un recubrimiento, dicho recubrimiento cubriendo por lo menos una porción de dicho núcleo y teniendo un lustre de superficie de por lo menos 150 unidades de lustre, en donde el recubrimiento comprende: a) aproximadamente de 10 por ciento a 70 por ciento de un formador de película comprendido de un polímero o copolímero de ácido acrílico o un derivado del mismo, o una mezcla del polímero o copolímero de ácido acrílico o un derivado del mismo; b) aproximadamente de 2 por ciento a 20 por ciento de

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un plastificante primario comprendido de un parabeno; y c) aproximadamente de 1 por ciento a 50 por ciento de un plastificante secundario seleccionado del grupo que consiste de polivinilpirrolidona, polietilenglicol 300, polietilenglicol 400, sales farmacéuticamente aceptables de los mismos y sus mezclas.

23.- Un medicamento de tipo cápsula simulada, que comprende: a) un núcleo que tiene un primer extremo y un segundo extremo; b) una primera capa de recubrimiento que tiene una primera distinción visual provista sobre dicho primer extremo de dicho núcleo de tableta; y c) una segunda capa de recubrimiento que tiene una segunda distinción visual sobre dicho segundo extremo de dicho núcleo de tableta; en donde por lo menos una de la primera capa de recubrimiento y la segunda capa de recubrimiento está comprendida de la composición que se reclama en la reivindicación 1.

24.- El medicamento de conformidad con la reivindicación 23, caracterizado además porque la segunda distinción visual es visualmente diferente de dicha primera distinción visual.

25.- El medicamento de conformidad con la reivindicación 24, caracterizado además porque la primera distinción visual es un primer color, y la segunda distinción visual es un segundo color.

26.- El medicamento de conformidad con la reivindicación 23, caracterizado además porque comprende una subcapa de recubrimiento que cubre sustancialmente dicho núcleo; dicha subcapa de recubrimiento estando provista entre dicho núcleo y dicha primera capa de recubrimiento y dicha segunda capa de recubrimiento.

27.- El medicamento de conformidad con la reivindicación 26, caracterizado además porque la subcapa de recubrimiento se selecciona del grupo que consiste de éteres de celulosa, plastificantes, policarbohidratos, pigmentos, opacantes, y mezclas de los mismos.

28.- La composición formadora de película de conformidad con la reivindicación 1, caracterizada además porque comprende, en base al peso total de la composición, aproximadamente de 0.01 por ciento a 0.25 por ciento de un incrementador de ganancia de peso.

29.- La composición formadora de película de conformidad con la reivindicación 28, caracterizada además porque el incrementador de ganancia de peso es simeticona, polisorbato 80, o mezclas de los mismos.

30.- Un método para aumentar la ganancia de peso de una capa de recubrimiento seca sobre un substrato moldeado por inmersión, que comprende agregar al recubrimiento una cantidad efectiva de un incrementador de ganancia de peso seleccionado de simeticona, polisorbato 80 y mezclas de los mismos, en donde el recubrimiento está comprendido de la composición que se reclama en la reivindicación 1.

31.- Un método para mejorar la uniformidad de color de una capa de recubrimiento seca sobre un substrato moldeado por inmersión, que comprende agregar a una dispersión acuosa de la composición de recubrimiento una cantidad efectiva de simeticona, polisorbato 80, o una mezcla de los mismos, en donde la composición de recubrimiento está comprendida de la composición que se reclama en la reivindicación 1.

32.- La composición de conformidad con la reivindicación 1, caracterizada además porque el formador de película es una mezcla que comprende un polímero o copolímero de ácido acrílico o un derivado del mismo.

33.- La composición de conformidad con la reivindicación 1, caracterizada además porque el formador de película es un copolímero que comprende un polímero o copolímero de ácido acrílico o un derivado del mismo.

34.- Una composición formadora de película que comprende, en base al peso total de sólidos secos de la composición: a) aproximadamente de 10 por ciento a 70 por ciento de un formador de película comprendido de un polímero o copolímero de ácido acrílico o un derivado del mismo, o una mezcla del polímero o copolímero de ácido acrílico o su derivado; y b) aproximadamente de 3 por ciento a 70 por ciento de un plastificante seleccionado del grupo que consiste de triacetina, monoglicérido acetilado, aceite de colza, aceite de oliva, aceite de ajonjolí, citrato de acetiltributilo, glicerina, sorbitol, oxalato de dietilo, malato de dietilo, fumarato de dietilo, succinato de dibutilo, malonato de dietilo, ftalato de dioctilo, succinato de dibutilo, citrato de trietilo, citrato de tributilo, tributirato de glicerol, propilenglicol, polietilenglicoles, aceite de ricino hidrogenado, ácidos grasos, triglicéridos y glicéridos sustituidos, metilparabeno, etilparabeno, propilparabeno, butilparabeno, polivinilpirrolidona, polietilenglicol 300, polietilenglicol 400, sales farmacéuticamente aceptables de los mismos, y

mezclas de los mismos; en donde la composición tiene un lustre de superficie de por lo menos 150 cuando se aplica a un substrato mediante recubrimiento de inmersión.

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PA 1045651

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

July 31, 2003

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: ***10/211,139***
FILING DATE: ***August 02, 2002***

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

L. Edelen

L. EDELEN
Certifying Officer

Please type a plus sign (+) inside this box [+]

UTILITY PATENT APPLICATION TRANSMITTAL (only for new nonprovisional applications under 37 CFR 1.53(b))	Attorney Docket No.	MCP-324
	First Inventor	Satish Kamath
	Title	POLYACRYLIC FILM FORMING COMPOSITIONS
	Express Mail Label No.	EV 065841424 US

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO: Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(submit an original and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.
3. ☒ Specification [Total Pages - 26]
(Preferred arrangement set forth below)
- Descriptive Title of the Invention
- Cross Reference to Related Applications
- Statement Regarding Fed sponsored R&D
- Reference to sequence listing, a table, or a computer program listing appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

4. ☒ Drawing(s)*(35 USC 113)* [Total Sheets -1]
5. Oath or Declaration [Total Pages - 3]
a. ☒ Unexecuted
b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).

6. ☐ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)

8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
a. ☐ Computer Readable Form (CRF)
b. ☐ Specification Sequence Listing on:
i. ☐ CD-ROM or CD-R (2 copies); or
ii. ☐ paper
c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney *(when there is an assignee)*
11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☐ Request and Certifications under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☒ Other - Express Mail Certificate

18. ☐ If a CONTINUING APPLICATION, *check appropriate box and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:*
☐ Continuation ☐ Divisional ☐ Continuation-in-Part (CIP) of prior application No.: , filed .
Prior application Information: Examiner Group Art Unit:
For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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NAME	Michele G. Mangini	Reg. No. 36,806
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DATE	August 2, 2002	

[redacted]

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10211139.030202 82

FEE TRANSMITTAL	Complete if Known	
	Application Number	
	Filing Date	2 August 2002
	First Named Inventor	Satish Kamath
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	MCP-324

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $740.00
TOTAL CLAIMS	34 - 20 =	14	x 18.00	$252.00
INDEPENDENT CLAIMS	3 - 3 =	0	x 84.00	$ 0.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	$280.00	
			TOTAL FEES	$ 992.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/MCP-324/MGM in the amount of 992.00. Three copies of this sheet are enclosed.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-0750/MCP-324/MGM. Three copies of this sheet are enclosed.

SUBMITTED BY:			Complete (if applicable)
Typed or Printed Name	Michele G. Mangini		Reg. No. 36,806
Signature	Michele G. Mangini	Date: 8/2/02	Deposit Account No. 10-0750

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DOCKET NO. MCP-324

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicant: Satish Kamath

For : POLYACRYLIC FILM FORMING COMPOSITIONS

Express Mail Certificate

"Express Mail" mailing number: EV 065841424 US

Date of Deposit: August 2, 2002

I hereby certify that this complete application, (including 26 specification pages, 34 claims, and one sheet of formal drawing), Declaration and Power of Attorney (unexecuted), and two pages of transmittal, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

A Combined Declaration and Power of Attorney will be submitted to the United States Patent and Trademark Office upon receipt of the U.S. Serial Number for this patent application.

Karen Hall-Morgan
(Typed or printed name of person mailing paper or fee)

Karen Hall-Morgan
(Signature of person mailing paper or fee)

[redacted]

POLYACRYLIC FILM FORMING COMPOSITIONS

FIELD OF THE INVENTION

This invention relates to novel, water soluble, gelatin-free compositions for coating substrates, such as tablets and capsules, and methods for producing such dosage forms. This invention further relates to a method for increasing the weight gain of a water soluble, gelatin-free, film forming coating on a dip-coated tablet or caplet.

BACKGROUND OF THE INVENTION

During most of this century, hard gelatin capsules were a popular dosage form for prescription and over-the-counter (OTC) drugs. The ability to combine capsule halves having different colors provided manufacturers with a unique means of distinguishing various pharmaceutical products. Many patients preferred capsules over tablets, perceiving them as being easier to swallow. This consumer preference prompted pharmaceutical manufacturers to market certain products in capsule form even when they were also available in tablet form.

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, 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.

An alternative to capsule products are caplets, which are solid, oblong tablets that may be coated with various polymers such as cellulose ethers to improve their aesthetics, stability, and swallowability. Typically, such polymers are applied to the tablets either from solution in organic solvents, or from aqueous dispersion via spraying. However, such spray-coated tablets lack the shiny surface and elegance of the hard gelatin capsules. Additionally, it is not commercially feasible to spray-coat a tablet with a different color coating on each end.

Another alternative to capsule products are "gelcaps," which are elegant, shiny, consumer-preferred dosage forms that are prepared by dipping each half of an elongated tablet in two different colors of gelatin solution. See United States Patent Nos.: 4,820,524; 5,538,125; 5,685,589; 5,770,225; 5,198,227; and 5,296,233, which are all incorporated by reference herein. A similar dosage form, commercially available as a "geltab," is prepared by dipping each half of a round, convex tablet into different colors of gelatin solution, as described in United States Patent Nos. 5,228,916, US 5,436,026 and US 5,679,406, which are all incorporated by reference herein. As used herein, such "gelcaps" and "geltabs" shall be included within the broader term, "tablets."

However, the use of gelatin as a pharmaceutical coating material presents certain disadvantages and limitations, including the potential for decreased dissolution rate after extended storage due to cross-linking of the gelatin, potential for microbial contamination of the gelatin

solution during processing, and long processing times due to extensive drying requirements. Further, the energy-related costs associated with gelatin coatings tend to be high since the gelatin material is typically applied to the substrates at an elevated temperature of at least about 40°C in order to maintain fluidity of the gelatin, while the substrates are maintained at about 50°C in order to minimize microbial growth.

Various attempts have been made to produce gelatin-free hard shell capsules. For example, WO 00/18835 discloses the combination of starch ethers or oxidized starch and hydrocolloids for use in preparing hard capsule shells via conventional dip molding processing. See also U.S. Pat. No. 4,001211 (capsules prepared via pin dip coating with thermogelled methylcellulose ether compositions). However, due to potential tampering concerns, hard gelatin capsules are no longer a preferred delivery system for consumer (over-the-counter) pharmaceuticals, dietary supplements, or other such products. Additionally, the properties of an ideal composition into which steel pins are to be dipped then dried to form hard capsule shells thereon are not necessarily the same as those for dipping tablets to form a coating thereon. For example, relevant physical properties such as viscosity, weight-gain, film thickness, tensile strength, elasticity, and moisture content will differ between compositions for hard capsule formation and for coating tablets. See e.g., U.S. Pat. No. 1,787,777 (Optimal temperatures of the substrate and coating solution, residence times in the solution, and drying conditions differ.)

One disadvantage associated with dipping tablets or capsules into a non-gelatin coating system is that the resulting coatings often lack adequate tensile strength, plasticity, hardness, and thickness. Moreover, the inclusion of plasticizers into such non-gelatin coating systems often results in tablets having soft, tacky coatings without a hardness sufficient to maintain their shape or smoothness during handling. In addition, many non-gelatin compositions do not adhere to the tablet substrate in an amount sufficient to uniformly cover the tablet after a single dipping. Further, many non-gelatin compositions lack the sufficient rheological properties necessary to maintain uniform color dispersion throughout the dipping and drying process. Although attempts have been made to improve the rheological properties of these compositions by, for example, increasing their solids content in order to increase viscosity. However, such compositions often disadvantageously resulted in undesirable coating aesthetics such as surface roughness, decreased gloss, and non-uniform coating thickness.

It is desirable to find a coating material, and in particular a dip coating material, which not only produces a similar elegant, shiny, high gloss, consumer-preferred dosage form similar to that of gelatin-coated forms, but which is absent the limitations of gelatin, particularly those noted above.

SUMMARY OF THE INVENTION

This invention relates to a film forming composition comprised of, consisting of, and/or consisting essentially of a film forming composition comprised of, consisting of, and/or consisting essentially of, based upon the total dry solids weight of the composition:

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or a derivative thereof, or a mixture of the polymer or copolymer of acrylic acid or a derivative thereof;

b) from about 2 percent to about 20 percent of a primary plasticizer comprised of a paraben; and

c) from about 1 percent to about 50 percent of a secondary plasticizer selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, pharmaceutically acceptable salts thereof, and mixtures thereof;

wherein the composition possesses a surface gloss of at least 150 gloss units when applied via dip coating to a substrate.

Another embodiment of the present invention is directed to a film forming composition comprised of, consisting of, and/or consisting essentially of, based upon the total dry solids weight of the composition:

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or a derivative thereof, or a mixture of the polymer or copolymer of acrylic acid or a derivative thereof; and

b) from about 3 percent to about 70 percent of a plasticizer selected from the group consisting of triacetin, acetylated monoglyceride, rape oil, olive oil, sesame oil, acetyltributyl citrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethyl fumarate, dibutyl succinate, diethylmalonate, dioctylphthalate, dibutylsuccinate, triethylcitrate, tributylcitrate, glyceroltributyrate, propylene glycol, polyethylene glycols, hydrogenated castor oil, fatty acids, substituted triglycerides and glycerides, methyl paraben, ethyl paraben, propyl paraben, butyl paraben, polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, and pharmaceutically acceptable salts thereof and mixtures thereof,

wherein the composition possesses a surface gloss of at least 150 when applied via dip coating to a substrate.

Yet another embodiment of the present invention is directed to a pharmaceutical dosage form comprising, consisting of, and/or consisting essentially of a core and a coating, said coating covering at least a portion of said core and having a surface gloss of at least 150 gloss units, wherein the coating comprises, consists of, and/or consists essentially of

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or a derivative thereof, or a mixture of the polymer or copolymer of acrylic acid or a derivative thereof;

b) from about 2 percent to about 20 percent of a primary plasticizer comprised of a paraben; and

c) from about 1 percent to about 50 percent of a secondary plasticizer selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, pharmaceutically acceptable salts thereof, and mixtures thereof.

We have found that when a dosage form is coated with the composition of the present invention, the result is an elegant, shiny, high gloss, consumer-preferred dosage form similar to that of a gelatin-coated form, but which lacks the limitations associated with gelatin, particularly those noted above. We have also found that when such a composition is used in dip coating and operations, it does not inhibit the dissolution of the active coated therewith. Further, we have found that the color uniformity of dosage forms coated with such compositions is improved upon the addition of a weight gain enhancer thereto.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 A is an enlarged, schematic top plan view of an oblong convex core of a first configuration, the bottom plan view being identical thereto;

FIG. 1B is an enlarged, schematic elevational side view of the oblong convex core of FIG. 1A, having a face 15, a "belly band" or side 11, and an edge or corner 12, the opposite elevational side view being identical thereto;

FIG. 2 is an enlarged, schematic elevational end view of the oblong convex core of FIGS. 1A and 1B, the opposite elevational end view being identical thereto;

FIG. 3 is a perspective view of an exemplary tablet 404 of the present invention having a first coating portion 412 of one visual distinction and a second coating portion 413 having a second visual distinction.

DETAILED DESCRIPTION OF THE INVENTION

As used herein, the term "dosage form" applies to any solid, semi-solid, or liquid composition designed to contain a specific pre-determined amount (dose) of a certain ingredient, such as, for example, an active ingredient as defined below. Suitable dosage forms may be in the form of pharmaceutical drug delivery systems, including those for oral administration, buccal administration, rectal administration, topical, transdermal, or mucosal delivery, or subcutaneous implants, or other implanted drug delivery systems; or compositions for delivering minerals, vitamins and other nutraceuticals, oral care agents, flavorants, and the like.

In one embodiment, the dosage form of the present invention may be in a solid form, yet may also contain liquid or semi-solid components therein.

In one embodiment, the dosage form may be an orally administered system for delivering a pharmaceutical active ingredient to the gastro-intestinal tract of a human. In another embodiment, the dosage form may be an orally administered "placebo" system consisting essentially of pharmaceutically inactive ingredients, which is designed to have the same visual appearance as a particular pharmaceutically active dosage form. Such "placebo" system dosage forms are suitable for use as as control dosage forms in clinical studies , and in particular, those studies designed for testing the safety and efficacy of a particular pharmaceutically active ingredient.

As used herein, "substrate" refers to a surface, layer or underlying base or support upon which another substance resides or acts, and "core" refers to a substrate that is at least partially

enveloped or surrounded by another material. As used herein, "capsules" refer to hard shell compartments that enclose a dosable ingredient. "Tablets," as used herein, refer to compressed or molded solid dosage forms of any shape or size. "Caplets," as used herein, refer to solid, oblong-shaped tablets. "Gelcaps" refer to solid caplets having a glossy gelatinous coating, and "geltabs" refer to solid tablets having flat sides, convex opposing faces, and a glossy gelatinous coating. "Hardness" as used herein in connection with films or coatings indicates the resistance of the film/coating to deformation upon impact. "Water soluble" or "water solubilize," as used herein in connection with non-polymeric materials, shall mean from sparingly soluble to very soluble, i.e., not more than 100 parts water required to dissolve 1 part of the non-polymeric, water soluble solute. See Remington, "The Science and Practice of Pharmacy," pages 208 – 209 (2000). "Water soluble" or "water solubilize," as used herein in connection with polymeric materials, shall mean that the polymer swells in water and can be dispersed at the molecular level to form a homogeneous dispersion or colloidal solution. "Surface gloss" as used herein, shall refer to amount of light reflectance as measured at a 60 degree incident angle using the method set forth in Example 4 herein.

Dimethicone is a well known pharmaceutical material consisting of linear siloxane polymers containing repeating units of the formula $\{-(CH_3)_2SiO\}_n$ stabilized with trimethylsiloxy end blocking units of the formula $[(CH_3)_3SiO-]$. Simethicone is the mixture of dimethicone and silicon dioxide. For the purposes of this invention, the two materials may be used interchangably.

The first embodiment of this invention is directed to water soluble, substantially gelatin-free, film forming compositions for coating tablets or other substrates. One composition comprises, consists of, and/or consists essentially of: a) a film former such as a polymer or copolymer of acrylic acid or derivative thereof such as methacrylic acid; b) a primary plasticizer such as a paraben; c) a secondary plasticizer such as polyvinylpyrrolidone, polyethylene glycol; and d) a solvent such as water. As used herein, "substantially gelatin-free" shall mean less than about 1 percent, e.g. less than about 0.5 percent, of gelatin in the composition.

The first component of the composition of the present invention is a film former, which may be comprised of acrylic-based polymers and copolymers, derivatives thereof, or mixtures thereof. "Copolymers," as used herein, shall mean a chemical compound or mixture thereof formed by polymerization and containing two or more repeating units. Examples of such film formers include those commercially available from Rohm Pharma GmbH, such as poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) in a 1:2:0.1 weight ratio available under the tradename, "Eudragit RS;" poly(methacrylic acid, methyl methacrylate) in a 1:2 weight ratio available under the tradename, "Eudragit S;" and poly(methacrylic acid, methyl methacrylate) in a 1:1 weight ratio available under the tradename, "Eudragit L." More specific examples of film formers that are commercially available from Rohm Pharma GmbH include, but are not limited to, poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride), which is available under the tradename, "Eudragit RS30D;" poly(methacrylic acid, ethyl acrylate), which is available under the tradename, "Eudragit L30D;" poly(ethyl acrylate, methyl methacrylate), which is available under the tradename "Eudragit NE30D;" poly(ethyl acrylate, methyl methacrylate,

trimethylammonioethyl methacrylate chloride, which is available under the tradename, "Eudragit RL;" and copolymers and mixtures thereof. Other film formers include, but are not limited to, polymers and copolymers of methacrylic acid, derivatives of polymers and copolymers of methacrylic acid such as ammoniomethacrylate copolymers, as well as copolymers thereof, derivatives thereof, and mixtures thereof.

In one embodiment, the composition includes a film former selected from the Eudragit RS30D polymer, the Eudragit RL30D polymer, copolymers thereof, and mixtures thereof. One suitable mixture may comprise Eudragit RS30D:Eudragit RL30D in about a 25:75 to about a 75:25 weight ratio.

The second component of the composition of the present invention is a plasticizer. Examples of suitable plasticizers include, but are not limited to triacetin, acetylated monoglyceride, rape oil, olive oil, sesame oil, acetyltributyl citrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethyl fumerate, dibutyl succinate, diethylmalonate, dioctylphthalate, dibutylsuccinate, triethylcitrate, tributylcitrate, glyceroltributyrate, propylene glycol, polyethylene glycols such as polyethylene glycol 300 and polyethylene glycol 400, hydrogenated castor oil, fatty acids, substituted triglycerides and glycerides, methyl paraben, ethyl paraben, propyl paraben, butyl paraben, polyvinylpyrrolidone, and pharmaceutically acceptable salts thereof and mixtures thereof.

In one embodiment the plasticizer includes a primary plasticizer, which may be selected from methyl paraben, ethyl paraben, propyl paraben, butyl paraben, and pharmaceutically acceptable salts thereof or mixtures thereof, and a secondary plasticizer , which may be selected from .polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, and pharmaceutically acceptable salts thereof, or mixtures thereof. Examples of suitable polyvinylpyrrolidones include but are not limited to that available from BASF Aktelngesellschaft under the tradenames, "PVP K30" or "PVP K90". The "K value" for the polyvinylpyrrolidone refers to the average molecular weight of the compound as discussed on page 15 of the "Polyvinylpyrrolidone for the Pharmaceutical Industry" brochure by BASF (August 1993), which is incorporated by referenced herein.

In one embodiment, the film forming composition for coating substrates may be substantially free of gelatin, i.e., e.g. contains less than about 1%, or less than about 0.01% of gelatin.

In another embodiment, the film forming composition for coating substrates may be substantially free of bovine derived materials, i.e., e.g. contains less than about 1%, or less than about 0.01% of bovine derived materials.

In one embodiment, the film forming composition for coating substrates contains, based upon the total dry solids weight of the composition, from about 10 percent to about 70 percent, e.g. from about 40 percent to about 65 percent, of a film former; and from about 3 percent to about 70 percent, e.g. from about 20 percent to about 50 percent, of a plasticizer.

In another embodiment, the film forming composition for coating substrates contains, based upon the total dry solids weight of the composition, from about 10 percent to about 70 percent, e.g. from about 40 percent to about 65 percent, of a film former; from about 2 percent to

about 20 percent, e.g. from about 5 percent to about 15 percent, of a primary plasticizer; and from about 1 percent to about 50 percent, e.g. from about 15 percent to about 35 percent, of a secondary plasticizer.

These film forming compositions are typically in the form of a dispersion for ease of dip coating substrates therein. Such dispersions contain a solvent in an amount, based upon the total weight of the dispersion, from about 65 percent to about 95 percent, for example, from about 75 percent to about 85 percent. Examples of suitable solvents include, but are not limited to water; alcohols such as methanol, ethanol, and isopropanol; organic solvents such as methylene chloride, acetone, and the like; and mixtures thereof. In one embodiment, the solvent is water. The resulting film forming dispersion typically possesses a solids level of, based upon the total weight of the film forming dispersion, from about 5 percent to about 35 percent, for example, from about 20 percent to about 30 percent.

In one embodiment, the film forming composition for coating substrates contains, based upon the total wet weight of the dipping dispersion composition, from about 2 percent to about 20 percent, e.g. from about 7 percent to about 15 percent, of a film former; from about 0.4 percent to about 5 percent, e.g. from about 1 percent to about 4 percent, of a primary plasticizer; from about 0.2 percent to about 12 percent, e.g. from about 2 percent to about 10 percent, of a secondary plasticizer; and from about 65 percent to about 95 percent, e.g. from about 70 percent to about 85 percent of water.

Optionally, the composition for coating substrates may further comprise other ingredients such as adjuvants and excipients, including opacifying agents, coloring agents, stabilizers, preservatives, flavorants, sweeteners and the like as known in the art. In one embodiment, the composition for coating substrates may further comprise, based upon the total weight of the dipping solution, from about 0 percent to about 14 percent opacifying agents such as titanium dioxide and/or colorants. See *Remington's Practice of Pharmacy*, Martin & Cook, 17th ed., pp. 1625 – 30, which is herein incorporated by reference.

Any coloring agent suitable for use in pharmaceutical applications may be used in the present invention and may include, but not be limited to azo dyes, quinopthalone dyes, triphenylmethane dyes, xanthene dyes, indigoid dyes, iron oxides, iron hydroxides, titanium dioxide, natural dyes, and mixtures thereof. More specifically, suitable colorants include, but are not limited to patent blue V, acid brilliant green BS, red 2G, azorubine, ponceau 4R, amaranth, D&C red 33, D+C red 22, D+C red 26, D+C red 28, D+C yellow 10, FD+C yellow 5, FD+C yellow 6, FD+C red 3, FD+C red 40, FD+C blue 1, FD+C blue 2, FD+C green 3, brilliant black BN, carbon black, iron oxide black, iron oxide red, iron oxide yellow, titanium dioxide, riboflavin, carotenes, antyhocyanines, turmeric, cochineal extract, clorophyllin, canthaxanthin, caramel, betanin, and mixtures thereof.

In one embodiment, the final product is a pharmaceutical dosage form comprised of a) a core; b) an optional subcoating layer that substantially covers the core; and c) an exterior coating layer that substantially covers the surface of the subcoating layer, the exterior coating layer comprised of the coating composition of the present invention. As used herein, "substantially

covers" shall mean at least about 95 percent of the underlying surface area of the substrate or core is covered by the coating. In such embodiments the dosage form typically comprises at least one active ingredient. One or more active ingredients may be contained in the core, the subcoating layer, the exterior coating layer, or any combination thereof. In one embodiment, at least one active ingredient is contained in the core.

In another embodiment, a first active ingredient may be contained in the subcoating layer, and the core may contain a second active ingredient and/or an additional amount of the first active ingredient. In yet another embodiment, the active ingredient may be contained in the subcoating layer, and the core may be substantially free, i.e., contain less than about 1 percent, e.g. less than about 0.1 percent, of active ingredient.

In another embodiment, the pharmaceutical dosage form is comprised of: a) a core; b) an optional subcoating layer on the surface of the core that covers a portion of the core; and c) an exterior coating layer that covers a portion of the surface of the subcoating layer, with the exterior coating layer comprised of the film forming composition of the present invention. The exterior coating layer may or may not be visually similar to the subcoating layer. As used herein, "portion" shall mean a part of the dosage form having a surface area that is equal to or less than about 95 percent of the surface area of the underlying substrate.

In yet a further embodiment, the exterior coating layer may be comprised of a plurality of coating portions. An example of this embodiment comprised of two exterior coating portions is illustrated in FIG. 2, in which the dosage form 404 is coated with a first exterior coating portion 412 and a second exterior coating portion 413. Although the dosage form in FIG. 2 indicates that at least one of such portions is visually and/or chemically distinct from at least one other portion, it is conceived that one or more of the portions may be visually and/or chemically similar in nature. For example, each end of a tablet may be coated with dip coatings of different colors to provide a distinctive appearance for specialty products. See United States Patent No. 4,820,524, which is incorporated by reference herein. In one such embodiment, the exterior coating layer comprises a first exterior coating portion and a second exterior coating portion which may be visually distinct from one another, for example the visually distinct portions may be of different colors, hues, glosses, reflective qualities, brightness, depth, shades, chroma, opacity, etc. For example, the shell may have a red portion and a yellow portion, or a flat finish portion and a glossy portion, or an opaque portion and a translucent portion.

Various types of substrates, e.g. cores, may be coated with the film forming composition of the present invention. The core or substrate may be any dosage form in need of a shiny, hard, and/or smooth surface. Examples of such coated substrates may nonexclusively result in the following products: pharmaceutical dosage forms, confectionery products, nutritional supplements, food stuffs, dyestuffs, dietary supplements, and the like.

The core, or substrate, of the present invention may be a solid or semi-solid dosage form of any size or shape. Suitable cores include compressed or molded tablets, hard or soft capsules, suppositories, and confectionery based forms which include, but are not limited to, lozenges, nougats, or fondants, and the like. For example, FIGS. 1A, 1B and 2 illustrate an oblong convex

core 10 having an oblong shape and two rounded ends 122, 144, as viewed from the top, bottom or sides (see FIGS. 1A and 1B). The oblong convex core 10 may also have two oppositely positioned convex surfaces 15, 15' and a raised portion therebetween, referred to as a land 20 (shown most clearly in FIGS. 1B and 2).

It is noted that the length of the oblong core 10 is an imaginary line (not shown per se, but which is commensurate with a portion of the dotted line 16 that is within the core 10 shown in FIG. 1B) which extends the distance between the ends 122, 144 of the oblong core 10. The height of the oblong core 10 is another imaginary line (not shown per se, but which is commensurate with a portion of the dotted line 18 that is within the core 10 shown in FIG. 1B) which extends the distance between the two opposite convex surfaces 15, 15' of the core 10, midway of the length. The width of the oblong core is a third imaginary line (not shown per se, but which is commensurate with a portion of the dotted line 16 that is within the core 10 shown in FIG. 2) which extends the distance between opposite sides of the core 10, perpendicular to and midway of the core's length and height (and which may intersect the land 20 of the core 10, if present).

The use of subcoatings is well known in the art and disclosed in, for example, United States Patent Nos. 3,185,626, which is incorporated by reference herein. Any composition suitable for film-coating a tablet may be used as a subcoating according to the present invention. Examples of suitable subcoatings are disclosed in United States Patent Nos. 4,683,256, 4,543,370, 4,643,894, 4,828,841, 4,725,441, 4,802,924, 5,630,871, and 6,274,162, which are all incorporated by reference herein. Additional suitable subcoatings include one or more of the following ingredients: cellulose ethers such as hydroxypropylmethylcellulose, hydroxypropylcellulose, and hydroxyethylcellulose; polycarbohydrates such as xanthan gum, starch, and maltodextrin; plasticizers including for example, glycerin, polyethylene glycol, propylene glycol, dibutyl sebecate, triethyl citrate, vegetable oils such as castor oil, surfactants such as polysorbate-80, sodium lauryl sulfate and dioctyl-sodium sulfosuccinate; polycarbohydrates, pigments, and opacifiers.

In one embodiment, the subcoating may be comprised of, based upon the total weight of the subcoating, from about 2 percent to about 8 percent, e.g. from about 4 percent to about 6 percent of a water-soluble cellulose ether and from about 0.1 percent to about 1 percent, castor oil, as disclosed in detail in United States Patent No. 5,658, 589, which is incorporated by reference herein. In another embodiment, the subcoating may be comprised of, based upon the total weight of the subcoating, from about 20 percent to about 50 percent, e.g., from about 25 percent to about 40 percent of HPMC; from about 45 percent to about 75 percent, e.g., from about 50 percent to about 70 percent of maltodextrin; and from about 1 percent to about 10 percent, e.g., from about 5 percent to about 10 percent of PEG 400.

The dried subcoating typically is present in an amount, based upon the dry weight of the core, from about 0 percent to about 5 percent. The dried dip coating layer typically is present in an amount, based upon the dry weight of the core and the optional subcoating, from about 1.5 percent to about 10 percent.

The average thickness of the dried exterior coating layer typically is from about 40 to about 400 microns. However, one skilled in the art would readily appreciate without undue experimentation that the exterior coating thickness may be varied in order to provide a smoother, easier to swallow, dosage form or to achieve a desired dissolution profile. In embodiments in which the exterior coating is applied by dipping, the thickness of dipped film coatings may vary at different locations on the substrate depending upon its shape. For example, the thickness of a gelatin dipped coating at an edge or corner (see, e.g., edge 12 in FIG. 1) of a substrate may be as much as 50 percent to 70 percent less than the thickness of that coating near the center of a major face of the substrate (see, e.g. face 15 in FIG. 1). This difference can be minimized by, for example, use of a thicker subcoating, or use of dipping compositions that result in higher weight gains on the substrate. However, unlike gelatin-based coatings, the coatings comprised of the composition of the present invention have relatively less variance in thickness when applied to a substrate, and in particular when applied via dip coating to the substrate.

In embodiments wherein a thicker dip coating is desired, we have found that an effective amount of a weight gain enhancer selected from the group consisting of simethicone, polysorbate 80 and mixtures thereof, may be added to the film forming composition. The weight gain enhancer is used in an amount sufficient to increase the weight gain of the coating solution, e.g. by at least about 10 percent, by at least about 20%, or by at least about 30 % on a substrate when dried. The percent weight gain increase is determined based upon the difference between the total weight of the coated substrate with the coating composition including the weight gain enhancer, and the total weight of an coated equivalent substrate, which has been coated under similar processing conditions with a coating composition that does not include an effective amount of weight gain enhancer.

A suitable film forming composition capable of achieving increased weight gain of dip coating on a substrate may contain, based upon the total dry weight of the film forming composition, from about 10 percent to about 70 percent, e.g. from about 40 percent to about 65 percent of an acrylic polymeric film former; from about 2 percent to about 20 percent , e.g. from about 5 percent to about 15 percent, of a primary plasticizer; from about 1 percent to about 50 percent , e.g. from about 15 percent to about 35 percent of a secondary plasticizer; and from about 0.01 percent to about 0.25 percent, e.g. from about 0.03 percent to about 0.15 percent of a weight gain enhancer. When aesthetics of the final tablet are of particular concern, it is recommended to not use greater than about 0.25 percent of a weight gain enhancer.

The film forming compositions of the present invention may be prepared by mixing all film formers under ambient conditions until the resulting mixture is homogeneous. The primary plasticizers are then added thereto at a temperature of about 55 °C to about 70 °C to form a first mixture. In an independent container, the secondary plasticizer is combined with the solvent in an amount sufficient to dissolve the secondary plasticizer and under ambient conditions. This mixture is then added to the first mixture at a temperature of about 55 °C to about 70 °C. Any remaining solvent and any optional ingredients such as colorants, opacifiers, the weight gain enhancer, or

other ingredients are then added thereto and mixed in the mixer until homogeneous under ambient conditions.

The film forming composition of the present invention may be applied to the substrate by any suitable method capable of producing a smooth film surface thereon. Examples of suitable methods include, but are not limited to molding or dipping. One suitable molding method includes forming a sheet of the film-forming composition, then enrobing the tablet therewith as described in, for example, U.S. Patent Nos. 5,146,730 and 5,459,983, which are incorporated by reference. Another suitable molding method includes introducing the film forming composition in a flowable form around a substrate in a mold cavity, then hardening the film-forming composition (e.g. by cooling), so as to form a coating on the substrate. After the dosage form is removed from the mold, it optionally may be dried. In one particular embodiment, the film forming composition of the invention may be injected through an orifice into a mold cavity, which contains the substrate.

It has surprisingly been found that substrates may be dipped into such dispersions of the present invention using the same equipment and similar range of process conditions as used for the production of dip molded, gelatin-coated tablets. For example, both tablets and hard capsules may be coated using the aqueous dispersions of the present invention via known gelatin-dipping process parameters and equipment. Details of such equipment and processing conditions are known in the art and are disclosed at, for example, United States Patent No. 4,820,524, which is incorporated by reference herein. Advantageously, because the coating solutions of the present invention are fluid at room temperature and are less susceptible to microbial growth than gelatin compositions, the dip coating process may occur under ambient temperature and pressure conditions.

The dosage forms coated with the composition of the present invention may contain one or more active agents. The term "active agent" is used herein in a broad sense and may encompass any material that can be carried by or entrained in the system. For example, the active agent can be a pharmaceutical, nutraceutical, vitamin, dietary supplement, nutrient, herb, foodstuff, dyestuff, nutritional, mineral, supplement, or favoring agent or the like and combinations thereof.

The active agents useful herein can be selected from classes from those in the following therapeutic categories: ace-inhibitors; alkaloids; antacids; analgesics; anabolic agents; anti-anginal drugs; anti-allergy agents; anti-arrhythmia agents; antiasthmatics; antibiotics; anticholesterolemics; anticonvulsants; anticoagulants; antidepressants; antidiarrheal preparations; anti-emetics; antihistamines; antihypertensives; anti-infectives; anti-inflammatories; antilipid agents; antimanics; anti-migraine agents; antinauseants; antipsychotics; antistroke agents; antithyroid preparations; anabolic drugs; antiobesity agents; antiparasitics; antipsychotics; antipyretics; antispasmodics; antithrombotics; antitumor agents; antitussives; antiulcer agents; anti-uricemic agents; anxiolytic agents; appetite stimulants; appetite suppressants; beta-blocking agents; bronchodilators; cardiovascular agents; cerebral dilators; chelating agents; cholecystekinin antagonists; chemotherapeutic agents; cognition activators; contraceptives; coronary dilators; cough suppressants; decongestants; deodorants; dermatological agents; diabetes agents; diuretics;

emollients; enzymes; erythropoietic drugs; expectorants; fertility agents; fungicides; gastrointestinal agents; growth regulators; hormone replacement agents; hyperglycemic agents; hypoglycemic agents; ion-exchange resins; laxatives; migraine treatments; mineral supplements; mucolytics, narcotics; neuroleptics; neuromuscular drugs; non-steroidal anti-inflammatories (NSAIDs); nutritional additives; peripheral vasodilators; polypeptides; prostaglandins; psychotropics; renin inhibitors; respiratory stimulants; sedatives; steroids; stimulants; sympatholytics; thyroid preparations; tranquilizers; uterine relaxants; vaginal preparations; vasoconstrictors; vasodilators; vertigo agents; vitamins; wound healing agents; and others.

Active agents that may be used in the invention include, but are not limited to: acetaminophen; acetic acid; acetylsalicylic acid, including its buffered forms; acrivastine; albuterol and its sulfate; alcohol; alkaline phosphatase; allantoin; aloe; aluminum acetate, carbonate, chlorohydrate and hydroxide; alprozolam; amino acids; aminobenzoic acid; amoxicillin; ampicillin; amsacrine; amsalog; anethole; ascorbic acid; aspartame; astemizole; atenolol; azatidine and its maleate; bacitracin; balsam peru; BCNU (carmustine); beclomethasone diproprionate; benzocaine; benzoic acid; benzophenones; benzoyl peroxide; benzquinamide and its hydrochloride; bethanechol; biotin; bisacodyl; bismuth subsalicylate; bornyl acetate; bromopheniramine and its maleate; buspirone; caffeine; calamine; calcium carbonate, caseinate and hydroxide; camphor; captopril; cascara sagrada; castor oil; cefaclor; cefadroxil; cephalexin; centrizine and its hydrochloride; cetirizine; cetyl alcohol; cetylpyridinium chloride; chelated minerals; chloramphenicol; chlorcyclizine hydrochloride; chlorhexidine gluconate; chloroxylenol; chloropentostatin; chlorpheniramine and its maleates and tannates; chlorpromazine; cholestyramine resin; choline bitartrate; chondrogenic stimulating protein; cimetidine; cinnamedrine hydrochloride; citalopram; citric acid; clarithromycin; clemastine and its fumarate; clonidine; clorfibrate; cocoa butter; cod liver oil; codeine and its fumarate and phosphate; cortisone acetate; ciprofloxacin HCl; cyanocobalamin; cyclizine hydrochloride; cyproheptadine; danthron; dexbromopheniramine maleate; dextromethorphan and its hydrohalides; diazepam; dibucaine; dichloralphenazone; diclofen and its alkali metal salts; diclofenac sodium; digoxin; dihydroergotamine and its hydrogenates/mesylates; diltiazem; dimethicone; dioxybenzone; diphenhydramine and its citrate; diphenhydramine and its hydrochloride; divalproex and its alkali metal salts; docusate calcium, potassium, and sodium; doxycycline hydrate; doxylamine succinate; dronabinol; efaroxan; enalapril; enoxacin; ergotamine and its tartrate; erythromycin; estropipate; ethinyl estradiol; ephedrine; epinephrine bitartrate; erythropoietin; eucalyptol; famotidine; fenoprofen and its metal salts; ferrous fumarate, gluconate and sulfate; fexofenadine; fluoxetine; folic acid; fosphenytoin; 5-fluorouracil (5-FU); fluoxetine; flurbiprofen; furosemide; gabapentan; gentamicin; gemfibrozil; glipizide; glycerine; glyceryl stearate; granisetron; griseofulvin; growth hormone; guafenesin; hexylresorcinol; hydrochlorothiazide; hydrocodone and its tartrates; hydrocortisone and its acetate; 8-hydroxyquinoline sulfate; hydroxyzine and its pamoate and hydrochloride salts; ibuprofen; indomethacin; inositol; insulin; iodine; ipecac; iron; isosorbide and its mono- and dinitrates; isoxicam; ketamine; kaolin; ketoprofen; lactic acid; lanolin; lecithin; leuprolide acetate; lidocaine and its hydrochloride salt; lifinopril; liotrix; loperamide, loratadine;

lovastatin; luteinizing hormone; LHRH (lutenizing hormone replacement hormone); magnesium carbonate, hydroxide, salicylate, and trisilicate; meclizine; mefenamic acid; meclofenamic acid; meclofenamate sodium; medroxyprogesterone acetate; methenamine mandelate; menthol; meperidine hydrochloride; metaproterenol sulfate; methscopolamine and its nitrates; methsergide and its maleate; methyl nicotinate; methyl salicylate; methyl cellulose; methauximide; metoclopramide and its halides/hydrates; metronidazole; metoprotol tartrate; miconazole nitrate; mineral oil; minoxidil; morphine; naproxen and its alkali metal sodium salts; nifedipine; neomycin sulfate; niacin; niacinamide; nicotine; nicotinamide; nimesulide; nitroglycerine; nonoxynol-9; norethindrone and its acetate; nystatin; octoxynol; octoxynol-9; octyl dimethyl PABA; octyl methoxycinnamate; omega-3 polyunsaturated fatty acids; omeprazole; ondansetron and its hydrochloride; oxolinic acid; oxybenzone; oxtriphylline; para-aminobenzoic acid (PABA); padimate-O; paramethadione; pentastatin; peppermint oil; pentaerythritol tetranitrate; pentobarbital sodium; perphenazine; phenetzine sulfate; phenindamine and its tartrate; pheniramine maleate; phenobarbital; phenol; phenolphthalein; phenylephrine and its tannates and hydrochlorides; phenylpropanolamine; phenytoin; pirmenol; piroxicam and its salts; polymicin B sulfate; potassium chloride and nitrate; prazepam; procainamide hydrochloride; procaterol; promethazine and its hydrochloride; propoxyphene and its hydrochloride and napsylate; pramiracetin; pramoxine and its hydrochloride salt; prochlorperazine and its maleate; propanolol and its hydrochloride; promethazine and its hydrochloride; propanolol; pseudoephedrine and its sulfates and hydrochlorides; pyridoxine; pyrolamine and its hydrochlorides and tannates; quinapril; quinidine gluconate and sulfate; quinestrol; ralitoline; ranitadine; resorcinol; riboflavin; salicylic acid; scopolamine; sesame oil; shark liver oil; simethicone; sodium bicarbonate, citrate, and fluoride; sodium monofluorophosphate; sucralfate; sulfamethoxazole; sulfasalazine; sulfur; sumatriptan and its succinate; tacrine and its hydrochloride; theophylline; terfenadine; thiethylperazine and its maleate; timolol and its maleate; thioperidone; tramadol; trimetrexate; triazolam; tretinoin; tetracycline hydrochloride; tolmetin; tolnaftate; triclosan; trimethobenzamide and its hydrochloride; tripelennamine and its hydrochloride; tripolidine hydrochloride; undecylenic acid; vancomycin; verapamil HCl; vidaribine phosphate; vitamins A, B, C, D, B_1, B_2, B_6, B_{12}, E, and K; witch hazel; xylometazoline hydrochloride; zinc; zinc sulfate; zinc undecylenate. Active agents may further include, but are not limited to food acids; insoluble metal and mineral hydroxides, carbonates, oxides, polycarbophils, and salts thereof; adsorbates of active drugs on a magnesium trisilicate base and on a magnesium aluminum silicate base, and mixtures thereof. Mixtures and pharmaceutically acceptable salts of these and other actives can be used.

In one embodiment, the dosage forms coated with the dip coatings of the present invention may be provided for immediate release of the active ingredient, i.e. the dissolution of the dosage form conformed to USP specifications for immediate release tablets containing the particular active ingredient employed. For example, for acetaminophen tablets, USP 24 specifies that in pH 5.8 phosphate buffer, using USP apparatus 2 (paddles) at 50 rpm, at least 80% of the acetaminophen contained in the dosage form is released therefrom within 30 minutes after dosing, and for ibuprofen tablets, USP 24 specifies that in pH 7.2 phosphate buffer, using USP apparatus

2 (paddles) at 50 rpm, at least 80% of the ibuprofen contained in the dosage form is released therefrom within 60 minutes after dosing. See USP 24, 2000 Version, 19 – 20 and 856 (1999).

We have unexpectedly found that the coatings, which were formed by applying the compositions of the present invention onto substrates, possessed excellent properties comparable to those possessed by gelatin coatings, e.g. crack resistance, hardness, thickness, color uniformity, smoothness, and gloss. In one embodiment, the exterior layer or "shell" of the present invention advantageously possesses a high surface gloss. The surface gloss of the shell and/or the exterior surface of the dosage form is at least about 150 gloss units, e.g. at least about 175 gloss units, or at least about 190 gloss units when measured by the method set forth in Example 4 herein.

In addition, substrates dip coated with the compositions of the present invention were superior to substrates dip coated with conventional gelatin-based coatings in several important ways. First, substrates dip coated with the compositions of the present invention advantageously retained acceptable dissolution characteristics for the desired shelf-life and storage period at elevated temperature and humidity conditions. In particular, the compositions according to the present invention were also advantageously more resistant to microbial growth, which thereby enabled a longer shelf-life or use-life of the dipping solution as well as a reduction in manufacturing cost. Second, the dried coatings comprised of the compositions of the present invention also surprisingly and advantageously contained fewer air bubbles relative to the amount present in dried, gelatin based dipping compositions, and possessed a relatively more uniform coating thickness, i.e., the thickness at the tablet edges 11 is comparable to that at the face 15 as shown in the tablet 10 illustrated in FIG. 2. Third, unlike dip processing with gelatin-containing compositions, substrates may optionally be dipped in the solutions of the present invention at room temperature, which is economically more beneficial. Fourth, the dip coated compositions of the present invention possessed a higher degree of glossiness relative to similar coatings applied via spray coating methods known in the art. The dip coated compositions of the present invention also possessed a similar degree of glossiness relative to that possessed by gelatin-containing dip or enrobing coatings, which are currently viewed as the industry benchmark for high gloss coatings. See, e.g., United States Patent No. 6,274,162 (Typical gloss readings for standard, commercially available gel-dipped or gelatin enrobed tablets range from about 200 to 240 gloss units, gloss readings for standard, commercially available sugar-coated medicaments range from 177 to 209 gloss units, and gloss readings for a new, high-gloss coating system range from about 148 to about 243 gloss units.).

We have further unexpectedly found that the addition of an effective amount of weight gain enhancer to the film forming composition of the present invention not only significantly increased the resulting dry weight of the dip coating on a substrate, but it also improved the color uniformity of the coating.

The invention illustratively disclosed herein suitably may be practiced in the absence of any component, ingredient, or step which is not specifically disclosed herein. Several examples are set

forth below to further illustrate the nature of the invention and the manner of carrying it out. However, the invention should not be considered as being limited to the details thereof.

EXAMPLES

Example 1.) Preparation of Dip Coating Dispersions

An aqueous dispersion containing the ingredients set forth in Table A was prepared:

Table A: Aqueous Dispersion Dipcoating Composition

Ingredient	Amount (g)
poly(ethyl acrylate, methyl methacrylate)trimethylammonioethyl methacrylate chloride from Rohm Pharma under the tradename, "Eudragit RL30D" *(30% dispersion)	100.0*
Methyl paraben	5.0
Polyvinylpyrollidone from BASF Aktiengesellschaft under the tradename, "K-90"	12.0
water	60.0
Red #55 dye	1.0
Red #40 lake	0.5
PEG 400	4.0
Total Solution Weight	182.5
solids in coating solution	52.5 g (28.78%)

A second aqueous dispersion containing the ingredients set forth in Table B was prepared:

Table B: Aqueous Dispersion Dipcoating Composition

Ingredient	Amount (g)
poly(ethyl acrylate, methyl methacrylate)trimethylammonioethyl methacrylate chloride from Rohm Pharma under the tradename, "Eudragit RL30D" (* 30% dispersion)	100.0*
Methyl paraben	5.0
Polyvinylpyrollidone from BASF Aktiengesellschaft under the tradename, "K-90"	12.0
water	110
"Opatint"® yellow color obtained from Colorcon, Inc.	3.0
PEG 400	4.0
Total Solution Weight	234
solids in coating solution	54 g (23.07%)

The red colorant-containing dispersion was independently prepared by placing the Eudragit RL30D in a 400 ml beaker, then adding 60 g of water followed by the 4 g of PEG 400

thereto under ambient conditions with mixing using a electric mixer (Janke and Kunkel, IKA Labortechnik, Staufen, Germany) with propeller blade at approximately 700 rpm. After adding the methylparaben thereto, the resulting solution was heated to 60 °C with constant mixing. While the resulting solution was cooling, the polyvinylpyrollidone was added thereto with mixing until dissolved. When the viscosity of the solution increased to the point that the vortex was no longer visually apparent, the speed of the mixer was increased to 1200 rpm. The colorants were added thereto with mixing until homogeneous. Each resulting solution was deaerated overnight under ambient conditions.

The yellow-colorant dispersion was made in an independent beaker in accordance with the same procedure, except with substitution of 110 g of water in place of the 60 g of water.

Example 2.) Preparation of Subcoating Dispersion

An aqueous dispersion containing the ingredients set forth in Table C was prepared by combining all of the ingredients in a beaker under ambient conditions.

Table C: Aqueous Dispersion Subcoating Composition

Ingredient	Part *
HPMC (2910, 5 mPa) from Dow Chemical Company under the tradename, "Methocel E-5"	20
Castor oil	1
Water	241.5
Total Coating Solution	262.5
% solids in coating solution	8%

* expressed in terms of part by weight unless otherwise noted

Example 3.) Preparation of Dipcoated Tablets

Compressed tablets were prepared in accordance with the procedure set forth in Example 1 of United States Patent No. 5,658,589 ("'589 Patent"), which was incorporated by reference herein.

The subcoating dispersion of Example 2 was then applied onto the compressed tablets via spraying in accordance with the procedure set forth in the examples of the '589 Patent . The dried subcoated tablets weighed an average of about 4.5% more than the subcoating-free tablets, i.e. the amount of subcoating was about 4.5% of the weight of the uncoated cores.

One half of each of these subcoated tablets were hand-dipped into the first dip coating dispersion of Example 1 for a dwell time of 1 second, removed from the dipping solution, then dried under ambient conditions. For each tablet, this process was repeated; the other half of each coated tablet was coated with the second dip coating dispersion of Example 1. The weight gain for these tablets is shown in Table D below:

Table D: % Weight Gain of Dried Subcoated Tablets

Tablet Number	Weight Increase (Yellow dip) (g)	Weight Increase (Red dip) (g)	Weight Increase (Yellow and Red dip combined) (g)
1	0.111	0.017	0.026
2	0.014	—	—
3	0.012	0.019	0.031
4	0.011	0.019	0.030
5	0.011	—	—
6	0.010	0.019	0.029
7	—	0.017	—
Average Weight Gained	0.011	0.018	0.030

This example showed that the tablets prepared in accordance with this example possessed an elegant, uniform color as well as good, uniform edge coverage. These tablets also were non-tacky and resembled gelatin-dip coated tablets.

Example 4.) Surface Gloss Measurement of Coated Tablets

Tablets made according to the preceding examples were tested for surface gloss using an instrument available from TriCor Systems Inc. (Elgin, IL) under the tradename, " Tri-Cor Model 805A/806H Surface Analysis System" and generally in accordance with the procedure described in "TriCor Systems WGLOSS 3.4 Model 805A/806H Surface Analysis System Reference Manual" (1996),which is incorporated by reference herein, except as modified below,

This instrument utilized a CCD camera detector, employed a flat diffuse light source, compared tablet samples to a reference standard, and determined average gloss values at a 60 degree incident angle. During its operation, the instrument generated a grey-scale image, wherein the occurrence of brighter pixels indicated the presence of more gloss at that given location.

The instrument also incorporated software that utilized a grouping method to quantify gloss, i.e., pixels with similar brightness were grouped together for averaging purposes.

The "percent full scale" or "percent ideal" setting (also referred to as the "percent sample group" setting), was specified by the user to designate the portion of the brightest pixels above the threshold that will be considered as one group and averaged within that group. "Threshold", as used herein, is defined as the maximum gloss value that will not be included in the average gloss value calculation. Thus, the background, or the non-glossy areas of a sample were excluded from the average gloss value calculations. The method disclosed in K. Fegley and C. Vesey, "The Effect of Tablet Shape on the Perception of High Gloss Film Coating Systems", which is available at www.colorcon.com as of 18 March, 2002 and incorporated by reference herein, was used in order to minimize the effects resulting from different tablet shapes, and thus report a metric that

was comparable across the industry.(Selected the 50% sample group setting as the setting which best approximated analogous data from tablet surface roughness measurements.).

After initially calibrating the instrument using a calibration reference plate (190-228; 294 degree standard; no mask, rotation 0, depth 0), a standard surface gloss measurement was then created using gel-coated caplets available from McNEIL-PPC, Inc. under the tradename, "Extra Strength Tylenol Gelcaps." The average gloss value for a sample of 112 of such gel-coated caplets was then determined, while employing the 25 mm full view mask (190-280), and configuring the instrument to the following settings:

Rotation: 0

Depth: 0.25 inches

Gloss Threshold: 95

% Full Scale: 50%

Index of Refraction: 1.57

The average surface gloss value for the reference standard was determined to be 269 gloss units.

Samples of coated tablets prepared according to the Example 2 were then tested in accordance with the same procedure. The surface gloss values that were obtained are summarized in Table E below.

Table E: Gloss values of coated tablets

Example No.	2
Type of coating	dipped
No. of tablets tested	2
Gloss Value (g.u.)	244

Additional samples of other, commercially available gel coated tablets were also tested in accordance with the same procedure and compared to the same standard. The results are summarized in Table F below.

Table F: Gloss values of commercially available coated tablets

Product	Motrin IB * Caplet (white)	Excedrin* * Aspirin free Caplets (red)	Excedrin ** Migraine Geltab (green side)	Excedrin ** Migraine Geltab (white side)	Extra Strength Tylenol Geltabs * (yellow side)	Extra Strength Tylenol Geltabs * (red side)
Type of coating	sprayed film	sprayed film	gelatin enrobed	gelatin enrobed	dipped	dipped
No. of tablets tested	41	40	10	10	112	112
Gloss Value(g.u.)	125	119	270	264	268	268

* Available from McNEIL-PPC, Inc.

** Available from Bristol-Myers, Squibb, Inc.

This Example showed that the tablets coated with the compositions of the present invention possessed a high surface gloss value that either was comparable to or exceeded that possessed by commercially –available gelatin coated tablets. In contrast, typical sprayed films possessed a substantially lower surface gloss, e.g. 119 to 125 in this Example.

Example 5.) Preparation of Dip Coating Dispersion with Simethicone

The dispersion having the formulation set forth below in Table G is prepared in accordance with the procedure set forth in Example 1, but with the simethicone being added to the mixture after the polyvinylpyrollidone is dissolved therein.

Table G: Aqueous Dispersion Subcoating Composition with Simethicone

Ingredient	Amount (g)
poly(ethyl acrylate, methyl methacrylate)trimethylammonioethyl methacrylate chloride from Rohm Pharma under the tradename, "Eudragit RL30D"	100.0
Methyl paraben	5.0
Polyvinylpyrollidone from BASF Aktiengesellschaft under the tradename, "K-90"	12.0
Simethicone	0.18g (0.15% of dry weight)
water	60.0
Red #55 dye	1.0
Red #40 lake	0.5
PEG 400	4.0
Total Solution Weight	182.8
% solids in coating solution	52.68 g (28.8%)

This Example is repeated with various amounts of simethicone ranging from, based upon the total dry weight of the film forming composition, about 0.03 to about 0.15 percent.

Example 6.) Preparation of Dip Coated Tablets

Tablets are subcoated with the subcoating of Example 2, then are dip coated with the dispersion of Example 5 using the procedure set forth in Example 3.

We claim:

1. A film forming composition comprised of, based upon the total dry solids weight of the composition:

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or a derivative thereof, or a mixture of the polymer or copolymer of acrylic acid or a derivative thereof;

b) from about 2 percent to about 20 percent of a primary plasticizer comprised of a paraben; and

c) from about 1 percent to about 50 percent of a secondary plasticizer selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, pharmaceutically acceptable salts thereof, and mixtures thereof;

wherein the composition possesses a surface gloss of at least 150 when applied via dip coating to a substrate.

2. The film forming composition of claim 1, wherein the film former is selected from the group consisting of

a) a polymer or copolymer of methacrylic acid or derivative thereof; and

b) mixtures of the polymer or copolymer of methacrylic acid or derivative thereof.

3. The film forming composition of claim 1, wherein the film former is ammoniomethacrylate copolymer.

4. The film forming composition of claim 1, wherein the film former is selected from the group consisting of :

a) poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) in a 1:2:0.1 weight ratio;

b) poly(methacrylic acid, methyl methacrylate) in a 1:2 weight ratio;

c) poly(methacrylic acid, methyl methacrylate) in a 1:1 weight ratio;

d) copolymers thereof; and

e) mixtures thereof.

5. The film forming composition of claim 1, wherein the film former is selected from the group consisting of :

a) poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride);

b) poly(methacrylic acid, ethyl acrylate);

c) poly(ethyl acrylate, methyl methacrylate);

d) poly(ethyl acrylate, methyl methacrylate)trimethylammonioethyl methacrylate chloride),

e) copolymers thereof; and

f) mixtures thereof.

8. The film forming composition of claim 1 wherein the paraben is selected from the group consisting of methyl paraben, ethyl paraben, propyl paraben, butyl paraben, pharmaceutically available salts thereof, and mixtures thereof.

7. The film forming composition of claim 1 wherein the secondary plasticizer is polyvinylpyrrolidone.

8. The film forming composition of claim 1, wherein the composition is substantially free of gelatin.

9. The composition of claim 1 further comprising, based upon the total dry weight of the composition, from about 0 percent to about 14 percent of a coloring agent.

10. The composition of claim 9 wherein the coloring agent is selected from the group consisting of azo dyes, quinopthalone dyes, triphenylmethane dyes, xanthene dyes, indigoid dyes, iron oxides, iron hydroxides, titanium dioxide, natural dyes, and mixtures thereof.

11. A product comprising an exterior coating, said exterior coating comprising the composition of claim 1.

12. A pharmaceutical dosage form comprising an exterior coating, said exterior coating comprising the composition of claim 1.

13. The pharmaceutical dosage form of claim 12 further comprising a plurality of exterior coatings, wherein at least a first portion of the dosage form is comprised of a first exterior coating and at least a second portion of the dosage form is comprised of a second exterior coating.

14. The pharmaceutical dosage form of claim 13 wherein the second exterior coating is visually distinct from the first exterior coating.

15. A pharmaceutical dosage form comprising a core, a subcoating substantially covering said core, and an exterior coating substantially covering said subcoating, wherein the exterior coating is comprised of the composition of claim 1.

16. The coated dosage form of claim 15 wherein the subcoating is selected from the group consisting of cellulose ethers, plasticizers, polycarbohydrates, pigments, opacifiers, and mixtures thereof.

17. A tablet dip coated with the film forming composition according to claim 1.

18. The pharmaceutical dosage form of claim 12 comprising an effective amount of a pharmaceutical active ingredient, wherein said dosage form meets USP dissolution requirements for immediate release forms of said pharmaceutical active ingredient.

19. A dispersion comprised of the composition of claim 1 and a solvent.

20. The dispersion of claim 19 comprised of, based upon the total weight of the dispersion,

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or derivatives thereof, or mixtures of a polymer or copolymer of acrylic acid or derivatives thereof;

b) from about 1 percent to about 40 percent of a primary plasticizer comprised of a paraben; and

c) from about 5 percent to about 20 percent of a secondary plasticizer selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, pharmaceutically acceptable salts thereof, and mixtures thereof; and

d) from about 5 percent to about 30 percent of water,

wherein the composition possesses a surface gloss of at least 150 when applied via dip coating to a substrate.

21. A method of making coated tablets comprising dip coating tablets with the aqueous dispersion of claim 20 under conditions sufficient.

22. A pharmaceutical dosage form comprising a core and a coating, said coating covering at least a portion of said core and having a surface gloss of at least 150 gloss units, wherein the coating comprises

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or a derivative thereof, or a mixture of the polymer or copolymer of acrylic acid or a derivative thereof;

b) from about 2 percent to about 20 percent of a primary plasticizer comprised of a paraben; and

c) from about 1 percent to about 50 percent of a secondary plasticizer selected from the group consisting of polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, pharmaceutically acceptable salts thereof, and mixtures thereof.

23. A simulated capsule-like medicament comprising:

a.) a core having a first end and a second end,

b.) a first coating layer having a first visual distinction provided on said first end of said tablet core; and

c.) a second coating layer having a second visual distinction on said second end of said tablet core;

wherein at least one of said first coating layer and second coating layer is comprised of the composition of claim 1.

24. The medicament of claim 23 wherein the second visual distinction is visually different from said first visual distinction.

25. The medicament of claim 24 wherein the first visual distinction is a first color, and the second visual distinction is a second color.

26. The medicament of claim 23 further comprising a subcoating layer substantially covering said core, said subcoating layer provided between said core and said first coating layer and said second coating layer.

27. The medicament of claim 26 wherein the subcoating is selected from the group consisting of cellulose ethers, plasticizers, polycarbohydrates, pigments, opacifiers, and mixtures thereof.

28. The film forming composition of claim 1 further comprising, based upon the total weight of the composition, from about 0.01 percent to about 0.25 percent of a weight gain enhancer.

29. The film forming composition of claim 28 wherein the weight gain enhancer is simethicone, polysorbate 80, or mixtures thereof.

30. A method for increasing the weight gain of a dried coating layer on a dip molded substrate comprised of adding an effective amount of weight gain enhancer selected from simethicone, polysorbate 80 and mixtures thereof to the coating wherein the coating is comprised of the composition of claim 1.

31. A method for improving the color uniformity of a dried coating composition layer on a dip molded substrate comprised of:

adding an effective amount of simethicone, polysorbate 80, or a mixture thereof to an aqueous dispersion of the coating composition, wherein the coating composition is comprised of the composition of claim 1.

32. The composition of claim 1 wherein the film former is a mixture comprising a polymer or copolymer of acrylic acid or derivative thereof.

33. The composition of claim 1 wherein the film former is a copolymer comprising a polymer or copolymer of acrylic acid or derivative thereof.

34. A film forming composition comprised of, based upon the total dry solids weight of the composition:

a) from about 10 percent to about 70 percent of a film former comprised of a polymer or copolymer of acrylic acid or a derivative thereof, or a mixture of the polymer or copolymer of acrylic acid or a derivative thereof; and

b) from about 3 percent to about 70 percent of a plasticizer selected from the group consisting of triacetin, acetylated monoglyceride, rape oil, olive oil, sesame oil, acetyltributyl citrate, glycerin sorbitol, diethyloxalate, diethylmalate, diethyl fumerate, dibutyl succinate, diethylmalonate, dioctylphthalate, dibutylsuccinate, triethylcitrate, tributylcitrate, glyceroltributyrate, propylene glycol, polyethylene glycols, hydrogenated castor oil, fatty acids, substituted triglycerides and glycerides, methyl paraben, ethyl paraben, propyl paraben, butyl paraben, polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400, and pharmaceutically acceptable salts thereof and mixtures thereof,

wherein the composition possesses a surface gloss of at least 150 when applied via dip coating to a substrate.

ABSTRACT OF THE INVENTION

Water soluble, gelatin-free dip coatings for substrates comprising an acrylic film former; a paraben plasticizer; and a secondary plasticizer such as polyvinylpyrrolidone, polyethylene glycol 300, polyethylene glycol 400 or mixtures thereof.

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DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		
☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required)	Attorney Docket Number	MCP-324
	First Named Inventor	Salah Kamath
	COMPLETE IF KNOWN	
	Application Number	
	Filing Date	2 August 2002
	Group Art Unit	
	Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

POLYACRYLIC FILM FORMING COMPOSITIONS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ is identified by Attorney Docket No. MCP-324, which appeared on the specification as filed on 2 August 2002..

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
		Patented Patented Patented

I hereby appoint:

☒ Practitioners at Customer Number 00002777 →

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☐ Practitioner(s) named below:

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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Address all telephone calls to Michele G. Mangini at telephone number (732) 524-2810.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 00002777 OR ☐ Correspondence address below

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[redacted]

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
NAME OF SOLE OR FIRST INVENTOR:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any]) Satish		Family Name or Surname KAMATH	
Inventor's Signature		Date	
Residence: City Hackettstown	State NJ	Country U.S.A.	Citizenship U.S.A.
Mailing Address 202 Winding Hills Drive			
City Hackettstown	State NJ	ZIP 07840	Country U.S.A.
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
NAME OF SECOND INVENTOR:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any])		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	ZIP	Country
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
NAME OF THIRD INVENTOR:	☐ A petition has been filed for this unsigned inventor		
Given Name (first and middle [if any])		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	ZIP	Country

FIG. 1A

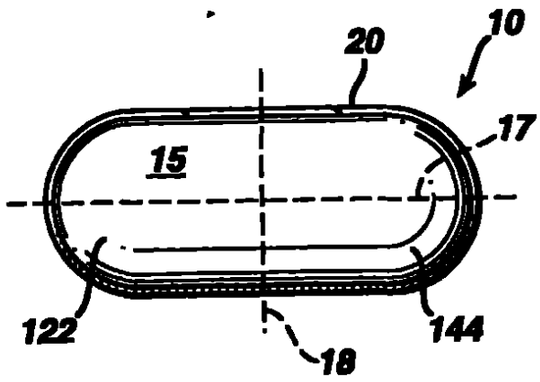

FIG. 1B

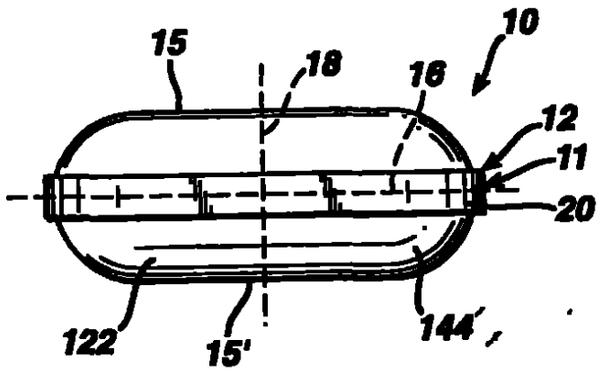

FIG. 2

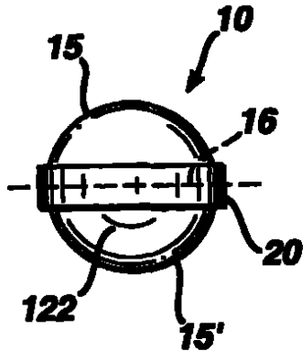

FIG. 3