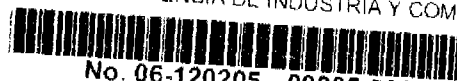


SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Art: 601 PRESENTAPODER Folios: 1

Señora

Alix Carmenza Céspedes de Vergel

Jefe de División de Nuevas Creaciones

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

E. S. D.

Referencia: Expediente No. 06.120.205

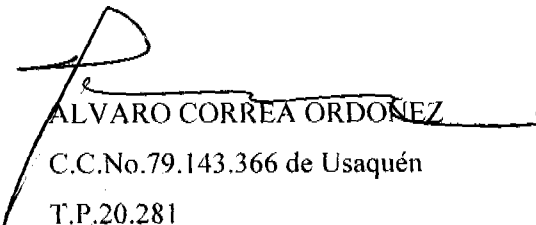
Solicitud de Patente de Invención titulada: "Formulación de tableta revestida y método"

Solicitante: Bristol-Myers Squibb Company

CAMBIO DE APODERADO

ALVARO CORREA ORDOÑEZ, mayor y vecino de Bogotá, D.C., identificado con la cédula de ciudadanía número 79.143.366 expedida en Bogotá, abogado inscrito con tarjeta profesional número 20.281 del Consejo Superior de la Judicatura, en mi carácter de apoderado de la sociedad de la referencia, presento poder otorgado por Bristol-Myers Squibb Company, el cual se encuentra radicado bajo el No. 08.129.339 del 04 de diciembre de 2008.

Atentamente,


ALVARO CORREA ORDOÑEZ

C.C.No.79.143.366 de Usaquén

T.P.20.281

COMPARECENCIA PERSONAL Y AUTENTICACION DE FIRMA

El Notario Treinta y Ocho (38) del Círculo de Bogotá, D.C. da fé que el anterior escrito dirigido a:

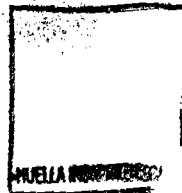
fué presentado personalmente por: ALVARO
CORDOBA ORDOÑEZ

quien exhibió la C.C. N°. 79143366 de USAQUEN
y T.P. N°. 20281 y manifestó que la firma y huella que aparece
en el presente documento son suyas, y que acepta el contenido del mismo

FIRMA

Eduardo Durán Gomez

NOTARIO 38 DEL CÍRCULO DE BOGOTÁ, D.C.



DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-120205

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

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **583** DE

FECHA **18 DE DICIEMBRE DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA

LEY EXPIRA EL **14 DE MARZO DE 2008**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____

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(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

Published:

— with international search report

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

(54) Title: STABLE PHARMACEUTICAL COMPOSITIONS COMPRISING ACE INHIBITOR(S)

(57) Abstract: The invention provides stable pharmaceutical compositions comprising ACE inhibitor(s) and other pharmaceutically active substances which are susceptible to degradation, as well as processes for the preparation thereof, and methods of treatment involving administration of such compositions.

WO 03/059330 A1

STABLE PHARMACEUTICAL COMPOSITIONS COMPRISING ACE INHIBITOR(S)

Field of the Invention

5 The present invention relates to stable pharmaceutical compositions comprising ace inhibitor(s), which are susceptible to degradation, and processes for the preparation thereof.

Background

10 Certain Angiotensin Converting Enzyme (ACE) inhibitors, which are useful as antihypertensives, are susceptible to certain types of degradation. ACE inhibitors such as ramipril, quinapril, enalapril, spirapril, lisinopril, benazepril and structurally related drugs can undergo cyclization via internal nucleophilic attack to form substituted
15 diketopiperazines. These drugs can also degrade via hydrolysis (of the side-chain ester group) and oxidation, to form products having unwanted coloration. It has been found that a significant cause of such degradations can be the mechanical stress associated with the manufacturing process of pharmaceutical composition such as compression. The stability of pharmaceutical compositions containing ACE inhibitors can also be negatively
20 influenced by the choice of tableting auxiliaries. In view of the usefulness of ACE inhibitors in treating hypertension, a number of research endeavors have been directed towards overcoming the inherent instability problem associated with ACE inhibitor-containing compositions.

For example United States Patent Nos. 4,743,450, 4,830,853, 4,793,998, international patent application WO 99/62560, European patent EP 468929 disclose
25 stabilization with various agents. United States Patent Nos. 5,151,433 and 5,442,008 disclose polymeric film-formers as protection against stress, as well as the use of buffers.

Thus, either addition of a stabilizer or a polymeric coat on the active ingredient is believed necessary to stabilize the pharmaceutical composition of ACE inhibitors, which are susceptible to degradation. However, the addition of such stabilizers can produce
30 unwanted pharmacological effects. Coating the active ingredient is quite cumbersome and low yielding moreover it requires specialized equipment.

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Summary

The applicants of the present invention have discovered a process making the use of the above unnecessary. Active ingredient, for example, an ACE inhibitor, which is susceptible to degradation, is applied as a coat to the core, preferably to a compressed core, thereby avoiding degradation (such as cyclization to diketopiperazine) induced by mechanical stress, which builds up during compression. Such an arrangement also avoids the direct contact of the tableting auxiliaries with the ACE inhibitor, thereby avoiding degradation by any incompatible tablet auxiliaries.

The present invention therefore allows greater flexibility in the choice of tableting auxiliaries. Moreover, as stabilizers are not required, untoward pharmacological effects, which could occur with the addition of such additives, are nullified. The process can be easily scaled up using the conventional tableting and coating equipment.

Therefore, the present invention can provide a stable pharmaceutical composition for oral administration of an ACE inhibitor comprising a core coated with a layer of ACE inhibitor(s) and process for preparation thereof.

Detailed Description

The core of the present invention is preferably a compressed core, which could be inert or may contain a drug other than the ACE inhibitor susceptible to degradation, such as hydrochlorothiazide, piretanide; and dihydropyridines such as felodipine, nitrendipine, nifedipine, lacidipine or other similar drugs. Alternatively the core may be a sugar or starch particle such as non-pareil sugar seeds, or pregelatinized starch. The core can be of any convenient shape, such as an spheroidal shape. The cores can range from about 25 mg to about 1 gram.

The compressed core may comprise diluent and other formulating agents such as binder, disintegrant, lubricant and glidant. The diluent may be, for example, any pharmaceutically acceptable, non-toxic diluent. Particular examples include lactose, dextrose, sucrose, maltose, microcrystalline cellulose, starch, calcium hydrogen phosphate, mannitol and the like.

Binders may be, for example, starch, sugars, gums, low molecular weight hydroxypropyl methylcellulose, hydroxypropylcellulose or the like. Disintegrant may be, for example, croscarmellose sodium, crospovidone, sodium starch glycolate, bentonite, sodium alginate, hydroxypropylmethylcellulose or the like. Lubricants may be, for example, talc, magnesium stearate, calcium stearate, hydrogenated vegetable oils, stearic

acid, sodium stearyl fumarate, sodium benzoate or the like. Glidants may be, for example, colloidal silicon dioxide (aerosil), talc or the like.

The ACE inhibitor layer comprises ACE inhibitor(s), which are susceptible to degradation, including ramipril, spirapril, lisinopril, enalapril, quinapril, benazepril and
5 other structurally related drugs. The process is applicable to other pharmaceutically active agents that are susceptible to mechanical stress-induced or mechanical stress-related degradation. The ACE inhibitor can be micronized, and suspended/dispersed in a solvent to which film forming polymer(s) is added. The film-forming polymer may be, for example, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose,
10 ethylcellulose, cellulose acetate, polyvinylpyrrolidone, gelatin, LustreClear™ (combination of microcrystalline cellulose and carrageenan), combinations of polyvinylalcohol and polyvinylacetate, and the like. The amount of the film forming polymer(s) can be relatively low, to limit the tablet/pellet/beadlet size and the manufacturing effort, but should be sufficient to effectively coat the drug on to the core.
15 The drug to polymer ratio may range from about 1:10 to about 10:1. For example, drug to polymer ratio can be from about 1:2 to about 2:1, or from about 1:1.2 to about 1.2:1, or, for example, about 1:1.

The polymer that is used for binding properties can also protect ACE inhibitors from atmospheric or chemical oxidation and degradation by agents such as atmospheric
20 humidity through, for example, hydrolysis.

The ACE inhibitor layer may optionally contain plasticizers, and is desirably without plasticizers. Stability can be undesirably lessened through the use of plasticizers. Plasticizers which may be excluded from the compositions include polyethyleneglycol, propylene glycol, triethyl citrate, triacetin, dibutylphthalate, diethylphthalate, castor oil,
25 tributyl citrate, glycerol, sorbitol, polysorbates, sorbitan esters and the like. The ACE inhibitor layer may also contain pigments, colorants, antifoaming agents, waxes, monoglycerides, emulsifiers, surfactants or other additives. The layer containing ACE inhibitor or other pharmaceutically active substance can contain such material from about 2% to about 90% by weight of the ACE inhibitor layer, and can also contain film-forming
30 polymer from about 10% to about 98% by weight of the ACE inhibitor layer.

Drug coating solution can be prepared in water, non-aqueous solvents or mixtures thereof. However desirably in water as stability can be lessened through the use of non-aqueous solvents. Solvents that may be excluded are isopropyl alcohol, acetone and methylene chloride.

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A seal coat may optionally separate the core and the ace inhibitor layer to completely seal the tableting auxiliaries to come in contact with the ACE inhibitor. Similarly, an outer coat may optionally be given on the ACE inhibitor layer to improve the aesthetic appeal of the tablet and to protect it from the atmospheric humidity. The seal
5 coat and outer coat may have the same composition as the ACE inhibitor layer except the drug, or it may have a different composition. For example, the seal coat may contain other polymers, such as Povidone. The seal coat can be prepared from aqueous dispersion of from about 2% to about 30% by weight of film-forming polymer.

The process of the present invention may be carried out in the following manner.
10 The compressed core can be prepared by conventional techniques such as direct compression, wet granulation and dry granulation.

The ACE inhibitor coating dispersion, suspension or solution can be prepared by adding the active ingredient(s) in a solvent with stirring or other mixing. Film forming polymer(s) and other additives can be added to the active ingredient dispersion with
15 stirring or other mixing. The cores are charged into a coating pan and warmed with air to an outlet-air temperature of, for example, about 30°C-45°C. The ACE inhibitor coating dispersion can be sprayed onto the cores and upon completion, the drug-coated tablets is dried, for example with dry air. Seal coat and outer coat dispersion may be prepared and applied in the similar manner as the ACE inhibitor layer, if required.

20 The coated tablets after air-drying can be packed into containers impervious to water vapor, e.g. blister packs (alu-alu; PVDC, PE, PVC-alu).

The tablets prepared by the present process may also be filed into capsules. The present process may also be applied to the non-pareil seeds or beadlets, which may then be filled in hard gelatin or starch capsules. Such capsules can have better stability as
25 compared to the conventional capsules.

The compositions disclosed herein may be formulated into solid dosage forms for oral administration, such as, for example, tablets, granules, capsules, pills, and the like. In these cases, the medicaments can be prepared by conventional methods, including a therapeutically effective amount of an ACE inhibitor or other pharmaceutically active
30 substance, and optionally but desirably, pharmaceutically acceptable excipients. In addition to the common dosage forms set out, the compositions may also be administered by controlled release means and/or delivery devices, with modifications known to those of ordinary skill in the art.

The compositions may, if desired, be presented in a pack or dispenser device, which may contain one or more unit dosage forms containing the active ingredient. The pack may for example comprise metal or plastic foil, such as a blister pack. The pack or dispenser device may be accompanied by instructions for administration.

5 By "therapeutically effective amount" is meant the quantity of a compound or composition according to the invention necessary to prevent, cure or at least partially arrest the symptoms of the disorder and its complications. Amounts effective to achieve this goal will, of course, depend on the severity of the disease and the weight and general state of the patient.

10

Methods of Treatment

The pharmaceutical compositions provided herein can be utilized for various treatment methods, such as those for treating hypertension, either alone or in combination with thiazide diuretics, as well as for use with stable patients who have demonstrated
15 clinical signs of congestive heart failure within the first few days after sustaining acute myocardial infarction, and also for left ventricular dysfunction and diabetic nephropathy.

The methods include administering to a mammal a therapeutically effective amount of a pharmaceutical composition as described herein.

The administration of pharmaceutical compositions can be by oral or buccal
20 administration,. Other methods of administration will be known to those skilled in the art.

Using the process parameters of the present invention, a convenient, reproducible stable pharmaceutical composition of the ACE inhibitors may be obtained. The present invention is further illustrative by, but is by no-means limited to, the following examples.

25

Examples

Example 1: Preparation of ACE inhibitor formulation

To prepare the tablet cores, in a non-shear blender, microcrystalline cellulose, Pregelatinised starch & Mannitol were mixed and to this mixture sodium stearyl fumarate was added and mixed. The mixture is then compressed to tablets of 100 mg each.

30

To prepare the seal coating solution, hydroxypropylmethylcellulose, hydroxypropylcellulose,(polyethylene glycol, titanium dioxide, and talc) were dispersed in water with stirring and the suspension homogenized.

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To prepare the drug coating suspension, ramipril was dispersed in water with stirring and to it hydroxypropylmethylcellulose, hydroxypropylcellulose, (polyethylene glycol, titanium dioxide, and talc) were added. The suspension was homogenized.

The outer-coating solution was prepared similar to the seal coat solution.

5 Tablet cores were placed in the coating pan (Hi-Coater) and heated with warm air to an air outlet temperature of about 30°C-45°C. The seal coating solution was sprayed on the cores. Upon completion the heating was discontinued but the air supply was maintained for about 10 minutes in order to dry the tablets.

10 The coated cores were sprayed with the drug coating solution and air dried maintaining the process parameters as for the seal coat. Similarly, the outer coating solution was then sprayed on the drug coated cores. The tablets were air dried and extracted from the apparatus and packed in suitable pack. The particular amounts of ingredients for various formulations are tabulated in Tables I, II III, IV and V. Tablets prepared according to the ingredients of these tables were prepared according to the
15 process described above.

Table I

INGREDIENT	WEIGHT(mg)
Core	
Mannitol	44.50
Microcrystalline cellulose	43.50
Pregelatinised starch	10.0
Sodium Stearyl Fumarate USNF	2.0
Tablet Weight	100.00
Seal Coat	2
Hydroxypropylmethylcellulose(67%)	
Hydroxypropylcellulose(6.7%)	
Polyethylene glycol(12%)	
Titanium dioxide(10%)	
Talc(6.3%)	
Purified water (q.s)	
Target Weight	102.00
Drug layer	
Ramipril	2.5
Film forming Polymer	2.5
Hydroxypropylmethylcellulose(67%)	
Hydroxypropylcellulose(6.7%)	
Polyethylene glycol(12%)	
Titanium dioxide(10%)	
Talc(6.3%)	
Purified water (q.s)	
Target Weight	107.00
Outer Coat	2.0
Hydroxypropylmethylcellulose(67%)	
Hydroxypropylcellulose(6.7%)	
Polyethylene glycol(12%)	
Titanium dioxide(10%)	
Talc(6.3%)	
Purified water (q.s)	
Total Weight	109.00

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**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES**

2020
Bogotá, D.C.,

Abogado:
ALVARO CORREA ORDOÑEZ

ASUNTO:	Radicación No.	06 12 0205
	Trámite	011
	Evento	378
	Actuación	430
	Oficio	3583
	Folios	

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

Documentos estudiados:

Descripción: Folios 30 a 56 como se radicó inicialmente.

Reivindicaciones: Folios 99 a 102 como se modificó en fase nacional.

Prioridad: US 60/575.319 (2004-05-28)

Objeto de la Invención

Título de la invención: "Formulación de tableta revestida y método"

Problema Técnico Planteado: "Necesidad de formulaciones farmacéuticas estable que contienen medicamentos los cuales son sometidos a ciclización intra-molecular, lo cual resulta en la formación de degradantes tales como amidinas cíclicas las cuales no son terapéuticamente activas."

Solución: "Proporcionar una tableta revestida la cual puede incluir un medicamento el cual es sometido a ciclización intra-molecular, estable a condiciones e almacenamiento normal como 30°C y 60% de humedad relativa"

IPC: A61K 9/24 AC; A61K 31/403 AC; A61P 3/10

Determinación del Estado de la Técnica

El Estado de la Técnica se determinó con base en la fecha de prioridad 2004-05-28 y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

114
112

Item	Documento	Título	Fecha de Publicación
D1	WO03059330	Stable pharmaceutical compositions comprising ACE inhibitors(s)	24.07.2003

Análisis de Patentabilidad (Art 14 D486)

Novedad (Art 16 D486)

La reivindicación 1 reclama una tableta revestida, caracterizada porque comprende un núcleo de tableta y componentes a), b) y c).

- a) una capa de revestimiento de sello interno cubierta en el núcleo de tableta;
- b) una segunda capa de revestimiento que comprende un medicamento revestido en el revestimiento de sello interno;
- c) opcionalmente una capa de revestimiento protector exterior, cubierta en la segunda capa de revestimiento del núcleo de tableta.

D1 revela núcleos comprimidos de una composición farmacéutica estable que contiene un inhibidor de ACE y comprende un núcleo recubierto con una capa de inhibidor de ACE y el proceso para su preparación (página 2).

Revela que la cubierta puede contener de 2 a 90% en peso de inhibidor de ACE (página 3), que la dispersión, solución o dispersión inhibidor puede ser preparado por adición de los ingredientes activos en un solvente con agitación o cualquier otro método de mezclado y aditivos como polímeros formadores de película pueden ser adicionados a la mezcla(página 4).

En el ejemplo 1, revela la secuencia de pasos que se realizaron para obtener las tabletas de la invención, y en base a dicho método presenta ejemplos específicos de las tabletas de la referencia que contienen un núcleo, una cubierta sellante, una capa de medicamento y una cubierta externa (página 7) tal y como se reclama en la presente solicitud.

Características esenciales de la Solicitud	D1
	WO03059330
tableta revestida, caracterizada porque comprende un núcleo de tableta	SI (página 2)
a) una capa de revestimiento de sello interno cubierta en el núcleo de tableta	SI (página 6 y 7)
b) una segunda capa de revestimiento que comprende un medicamento revestido en el revestimiento de sello interno	SI (página 6 y 7)
c) opcionalmente una capa de revestimiento protector exterior, cubierta en la segunda capa de revestimiento del núcleo de tableta	SI (página 6 y 7)

Se concluye que la reivindicación 1 reclama materia que podría carecer de novedad dado que el estado del arte ya anticipaba la tableta que se reclama y los métodos que se presentan.

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Conclusión

Los requisitos de Patentabilidad de la presente Solicitud se encuentran afectados así:

N°	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO03059330	1-16	Novedad

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de 60 días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única N° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha _____

CONCEPTO TECNICO NUMERO: 560	EXAMINADOR TÉCNICO Código:202092
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