comprising rosuvastatin or its salt and a layer comprising olmesartan medoxomil. In another embodiment, the pharmaceutical composition of the present invention has a tablet form consisting essentially of an inner core comprising rosuvastatin or its salt and an outer layer comprising olmesartan medoxomil. In still another embodiment, the pharmaceutical composition of the present invention has a capsule form filled with pellets comprising rosuvastatin or its salt and pellets comprising olmesartan medoxomil.

[9] In the pharmaceutical composition of the present invention, the compartment comprising rosuvastatin or its salt may comprise one or more disintegrant selected from the group consisting of ~~povidone,~~ crospovidone, low substituted hydroxypropyl cellulose, croscarmellose sodium, and carboxymethylcellulose calcium. The disintegrant may be present in an amount ranging from 2 to 20 % by weight, based on the total weight of the compartment comprising rosuvastatin or its salt.

[10] In the pharmaceutical composition of the present invention, the compartment comprising olmesartan medoxomil may comprise one or more disintegrant selected from the group consisting of low substituted hydroxypropyl cellulose, carboxymethylcellulose calcium, croscarmellose sodium, crospovidone, sodium starch glycolate, and pregelatinized starch. In an embodiment, the compartment comprising olmesartan medoxomil comprises 7.5 or more % by weight of low substituted hydroxypropyl cellulose, 5 or more % by weight of carboxymethylcellulose calcium, 15 or more % by weight of croscarmellose sodium, 10 or more % by weight of crospovidone, 5 or more % by weight of sodium starch glycolate, or 5 or more % by weight of pregelatinized starch, based on the total weight of the compartment comprising olmesartan medoxomil. In another embodiment, the compartment comprising olmesartan medoxomil comprises 7.5 to 65 % by weight of low substituted hydroxypropyl cellulose, 5 to 60 % by weight of carboxymethylcellulose calcium, 15 to 30 % by weight of croscarmellose sodium, 10 to 40 % by weight of crospovidone, 5 to 40 % by weight of sodium starch glycolate, or 5 to 60 % by weight of pregelatinized starch, based on the total weight of the compartment comprising olmesartan medoxomil. In still another embodiment, the compartment comprising olmesartan medoxomil comprises 7.5 to 65 % by weight, preferably 10 to 60 % by weight of low substituted hydroxypropyl cellulose, based on the total weight of the compartment comprising olmesartan medoxomil.

Advantageous Effects of Invention

[11] It was found by the present invention that, when rosuvastatin and olmesartan medoxomil are administered in a single matrix formulation, there is drug-drug interaction and/or drug-drug interference between rosuvastatin and olmesartan

consisting essentially of an inner core comprising rosuvastatin or its salt and an outer layer (or shell) comprising olmesartan medoxomil. In still another embodiment, the pharmaceutical composition of the present invention has a capsule form filled with pellets comprising rosuvastatin or its salt and pellets comprising olmesartan medoxomil.

[22] Meanwhile, it was found by the present invention that, even when olmesartan medoxomil and rosuvastatin or its salt were formulated into a combination dosage form having separate compartments according to a conventional formulation method, it was difficult to obtain a combination formulation bioequivalent to the single formulation of each of drugs. It is found by the present invention that, when the compartment comprising rosuvastatin or its salt includes a certain disintegrant, i.e., cellulose-type and/or povidone-type disintegrants, in a certain amount, rapid disintegration and high initial dissolution rate of rosuvastatin or its salt can be accomplished, thereby being able to obtain a combination formulation bioequivalent to the single formulation of rosuvastatin or its salt. The disintegrant may be one or more selected from the group consisting of ~~povidone (for example, Kolidone™, etc.),~~ crospovidone (for example, Polyplasdone™, etc.], low substituted hydroxypropyl cellulose, croscarmellose sodium, and carboxymethylcellulose calcium. Preferably, the disintegrant may be a mixture of crospovidone and croscarmellose sodium; or croscarmellose sodium. The disintegrant may be present in an amount ranging from 2 to 20 % by weight, preferably from 3 to 15 % by weight, based on the total weight of the compartment comprising rosuvastatin or its salt. When other disintegrants are used, the dissolution rate of rosuvastatin or its salt is decreased; and/or the amount used is increased, which may cause insufficient compression force during the compressing step, thereby leading to high friability of the resulting formulation (e.g., tablet). In addition, the use of other disintegrants brings about insufficient hardness, which may cause unwanted problems in e.g., packaging, delivery, etc.

[23] And also, it was found by the present invention that, in case of olmesartan medoxomil, a combination formulation comprising rosuvastatin and olmesartan medoxomil should be designed so as to exhibit higher dissolution rate (to non-equivalent level as a pharmaceutical equivalence criteria) of olmesartan medoxomil in an *in vitro* comparative dissolution test, in order to obtain a bioequivalent formulation to the single formulation containing olmesartan medoxomil. That is, the pharmaceutical composition of the present invention exhibits bioequivalence to the single formulation containing olmesartan medoxomil, although it shows non-equivalent *in vitro* dissolution rate. In order to obtain the non-equivalent *in vitro* dissolution rate, the compartment comprising olmesartan medoxomil comprise a certain disintegrant, which may be one or more selected from the group consisting of low substituted hy-

[97] **Example 6**

[98] Double-layered tablets comprising ~~carboxymethylcellulose calcium~~ as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 9. The amounts of the table 9 refer to the amounts per 1 tablet.

[99] Table 9

[Table 9]

	Components		Example			
			6-1	6-2	6-3	6-4
Rosuvastatin-containing layer (mg/tablet)	Active ingredient	rosuvastatin calcium	20.80	20.80	20.80	20.80
	Additive	lactose monohydrate	123.40	123.40	123.40	123.40
	Additive	Prosolv™	42.60	42.60	42.60	42.60
	Additive	dibasic calcium phosphate dihydrate	21.80	21.80	21.80	21.80
	Disintegrant	crospovidone	10.70	10.70	10.70	10.70
	Disintegrant	croscarmellose sodium	6.40	6.40	6.40	6.40
	Lubricant	light anhydrous silicic acid	4.30	4.30	4.30	4.30
	Lubricant	magnesium stearate	4.30	4.30	4.30	4.30
Olmesartan medoxomil-containing layer (mg/tablet)	Active ingredient	olmesartan medoxomil	40.00	40.00	40.00	40.00
	Binder	hydroxypropyl cellulose	10.00	10.00	10.00	10.00
	Additive	lactose monohydrate	284.27	263.27	200.27	179.27
	Additive	microcrystalline cellulose	40.00	40.00	40.00	40.00
	Disintegrant	croscarmellose sodium	42.00(10.0%)	63.00(15.0%)	126.00(30.0%)	179.27(35.0%)
	Lubricant	magnesium stearate	3.60	3.60	3.60	3.60

[100]

[101] **Example 7**

[102] Double-layered tablets comprising ~~carboxymethylcellulose calcium~~ as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 10. The amounts of the table 10 refer to the amounts per 1 tablet.

[103] Table 10

[Table 10]

	Components		Example			
			7-1	7-2	7-3	7-4
Rosuvastatin-containing layer (mg/tablet)	Active ingredient	rosuvastatin calcium	20.80	20.80	20.80	20.80
	Additive	lactose monohydrate	123.40	123.40	123.40	123.40
	Additive	Prosolv™	42.60	42.60	42.60	42.60
	Additive	dibasic calcium phosphate dihydrate	21.80	21.80	21.80	21.80
	Disintegrant	crospovidone	10.70	10.70	10.70	10.70
	Disintegrant	croscarmellose sodium	6.40	6.40	6.40	6.40
	Lubricant	light anhydrous silicic acid	4.30	4.30	4.30	4.30
	Lubricant	magnesium stearate	4.30	4.30	4.30	4.30
Olmesartan medoxomil-containing layer (mg/tablet)	Active ingredient	olmesartan medoxomil	40.00	40.00	40.00	40.00
	Binder	hydroxypropyl cellulose	10.00	10.00	10.00	10.00
	Additive	lactose monohydrate	294.77	284.27	158.27	137.27
	Additive	microcrystalline cellulose	40.00	40.00	40.00	40.00
	Disintegrant	crospovidone	31.50(7.50%)	42.00(10.0%)	168.00(40.0%)	189.00(45.0%)
	Lubricant	magnesium stearate	3.60	3.60	3.60	3.60

[104]

[105] **Example 8**

[106] Double-layered tablets comprising ~~carboxymethylcellulose calcium~~ as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 11. The amounts of the table 11 refer to the amounts per 1 tablet.

[107] Table 11

[Table 11]

	Components		Example			
			8-1	8-2	8-3	8-4
Rosuvastatin-containing layer (mg/tablet)	Active ingredient	rosuvastatin calcium	20.80	20.80	20.80	20.80
	Additive	lactose monohydrate	123.40	123.40	123.40	123.40
	Additive	Prosolv™	42.60	42.60	42.60	42.60
	Additive	dibasic calcium phosphate dihydrate	21.80	21.80	21.80	21.80
	Disintegrant	crospovidone	10.70	10.70	10.70	10.70
	Disintegrant	croscarmellose sodium	6.40	6.40	6.40	6.40
	Lubricant	light anhydrous silicic acid	4.30	4.30	4.30	4.30
	Lubricant	magnesium stearate	4.30	4.30	4.30	4.30
Olmesartan medoxomil-containing layer (mg/tablet)	Active ingredient	olmesartan medoxomil	40.00	40.00	40.00	40.00
	Binder	hydroxypropyl cellulose	10.00	10.00	10.00	10.00
	Additive	lactose monohydrate	315.77	305.77	158.27	137.27
	Additive	microcrystalline cellulose	40.00	40.00	40.00	40.00
	Disintegrant	sodium starch glycolate	10.50(2.5%)	21.00(5.0%)	168.00(40.0%)	189.00(45.0%)
	Lubricant	magnesium stearate	3.60	3.60	3.60	3.60

[108]

[109] **Example 9**

[110] Double-layered tablets comprising ~~carboxymethylcellulose calcium~~ as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 12. The amounts of the table

Claims

[Claim 1] A pharmaceutical composition having a single dosage form comprising a compartment comprising olmesartan medoxomil; and a compartment comprising rosuvastatin or its salt, wherein said compartments are formulated in a separate form.

[Claim 2] The pharmaceutical composition according to claim 1, having a double-layered tablet form, a tablet form consisting essentially of an inner core and an outer layer, or a pellet-containing capsule form.

[Claim 3] The pharmaceutical composition according to claim 1, having a double-layered tablet form consisting essentially of a layer comprising rosuvastatin or its salt and a layer comprising olmesartan medoxomil.

[Claim 4] The pharmaceutical composition according to claim 1, having a tablet form consisting essentially of an inner core comprising rosuvastatin or its salt and an outer layer comprising olmesartan medoxomil.

[Claim 5] The pharmaceutical composition according to claim 1, having a capsule form filled with pellets comprising rosuvastatin or its salt and pellets comprising olmesartan medoxomil.

[Claim 6] The pharmaceutical composition according to any one of claims 1 to 5, wherein the compartment comprising rosuvastatin or its salt comprises one or more disintegrant selected from the group consisting of povidone, crospovidone, low substituted hydroxypropyl cellulose, croscarmellose sodium, and carboxymethylcellulose calcium.

[Claim 7] The pharmaceutical composition according to claim 6, wherein the disintegrant is present in an amount ranging from 2 to 20 % by weight, based on the total weight of the compartment comprising rosuvastatin or its salt.

[Claim 8] The pharmaceutical composition according to any one of claims 1 to 5, wherein the compartment comprising olmesartan medoxomil comprises one or more disintegrant selected from the group consisting of low substituted hydroxypropyl cellulose, carboxymethylcellulose calcium, croscarmellose sodium, crospovidone, sodium starch glycolate, and pregelatinized starch.

[Claim 9] The pharmaceutical composition according to claim 8, wherein the compartment comprising olmesartan medoxomil comprises 7.5 or more % by weight of low substituted hydroxypropyl cellulose, 5 or more % by weight of carboxymethylcellulose calcium, 15 or more % by weight of croscarmellose sodium, 10 or more % by weight of crospovidone, 5

or more % by weight of sodium starch glycolate, or 5 or more % by weight of pregelatinized starch, based on the total weight of the compartment comprising olmesartan medoxomil.

[Claim 10] The pharmaceutical composition according to claim 8, wherein the compartment comprising olmesartan medoxomil comprises 7.5 to 65 % by weight of low substituted hydroxypropyl cellulose, 5 to 60 % by weight of carboxymethylcellulose calcium, 15 to 30 % by weight of croscarmellose sodium, 10 to 40 % by weight of crospovidone, 5 to 40 % by weight of sodium starch glycolate, or 5 to 60 % by weight of pregelatinized starch, based on the total weight of the compartment comprising olmesartan medoxomil.

[Claim 11] The pharmaceutical composition according to claim 8, wherein the compartment comprising olmesartan medoxomil comprises 7.5 to 65 % by weight of low substituted hydroxypropyl cellulose, based on the total weight of the compartment comprising olmesartan medoxomil.

[Claim 12] The pharmaceutical composition according to claim 8, wherein the compartment comprising olmesartan medoxomil comprises 10 to 60 % by weight of low substituted hydroxypropyl cellulose, based on the total weight of the compartment comprising olmesartan medoxomil.

[97] **Example 6**

[98] Double-layered tablets comprising croscarmellose sodium as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 9. The amounts of the table 9 refer to the amounts per 1 tablet.

[99] Table 9

[Table 9]

	Components		Example			
			6-1	6-2	6-3	6-4
Rosuvastatin-containing layer (mg/tablet)	Active ingredient	rosuvastatin calcium	20.80	20.80	20.80	20.80
	Additive	lactose monohydrate	123.40	123.40	123.40	123.40
	Additive	Prosolv™	42.60	42.60	42.60	42.60
	Additive	dibasic calcium phosphate dihydrate	21.80	21.80	21.80	21.80
	Disintegrant	crospovidone	10.70	10.70	10.70	10.70
	Disintegrant	croscarmellose sodium	6.40	6.40	6.40	6.40
	Lubricant	light anhydrous silicic acid	4.30	4.30	4.30	4.30
	Lubricant	magnesium stearate	4.30	4.30	4.30	4.30
Olmesartan medoxomil-containing layer (mg/tablet)	Active ingredient	olmesartan medoxomil	40.00	40.00	40.00	40.00
	Binder	hydroxypropyl cellulose	10.00	10.00	10.00	10.00
	Additive	lactose monohydrate	284.27	263.27	200.27	179.27
	Additive	microcrystalline cellulose	40.00	40.00	40.00	40.00
	Disintegrant	croscarmellose sodium	42.00(10.0%)	63.00(15.0%)	126.00(30.0%)	179.27(35.0%)
	Lubricant	magnesium stearate	3.60	3.60	3.60	3.60

[100]

[101] **Example 7**

[102] Double-layered tablets comprising crospovidone as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 10. The amounts of the table 10 refer to the amounts per 1 tablet.

[103] Table 10

[Table 10]

	Components		Example			
			7-1	7-2	7-3	7-4
Rosuvastatin-containing layer (mg/tablet)	Active ingredient	rosuvastatin calcium	20.80	20.80	20.80	20.80
	Additive	lactose monohydrate	123.40	123.40	123.40	123.40
	Additive	Prosolv™	42.60	42.60	42.60	42.60
	Additive	dibasic calcium phosphate dihydrate	21.80	21.80	21.80	21.80
	Disintegrant	crospovidone	10.70	10.70	10.70	10.70
	Disintegrant	croscarmellose sodium	6.40	6.40	6.40	6.40
	Lubricant	light anhydrous silicic acid	4.30	4.30	4.30	4.30
	Lubricant	magnesium stearate	4.30	4.30	4.30	4.30
Olmesartan medoxomil-containing layer (mg/tablet)	Active ingredient	olmesartan medoxomil	40.00	40.00	40.00	40.00
	Binder	hydroxypropyl cellulose	10.00	10.00	10.00	10.00
	Additive	lactose monohydrate	294.77	284.27	158.27	137.27
	Additive	microcrystalline cellulose	40.00	40.00	40.00	40.00
	Disintegrant	crospovidone	31.50(7.50%)	42.00(10.0%)	168.00(40.0%)	189.00(45.0%)
	Lubricant	magnesium stearate	3.60	3.60	3.60	3.60

[104]

[105] **Example 8**

[106] Double-layered tablets comprising sodium starch glycolate as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 11. The amounts of the table 11 refer to the amounts per 1 tablet.

[107] Table 11

[Table 11]

	Components		Example			
			8-1	8-2	8-3	8-4
Rosuvastatin-containing layer (mg/tablet)	Active ingredient	rosuvastatin calcium	20.80	20.80	20.80	20.80
	Additive	lactose monohydrate	123.40	123.40	123.40	123.40
	Additive	Prosolv™	42.60	42.60	42.60	42.60
	Additive	dibasic calcium phosphate dihydrate	21.80	21.80	21.80	21.80
	Disintegrant	crospovidone	10.70	10.70	10.70	10.70
	Disintegrant	croscarmellose sodium	6.40	6.40	6.40	6.40
	Lubricant	light anhydrous silicic acid	4.30	4.30	4.30	4.30
	Lubricant	magnesium stearate	4.30	4.30	4.30	4.30
Olmesartan medoxomil-containing layer (mg/tablet)	Active ingredient	olmesartan medoxomil	40.00	40.00	40.00	40.00
	Binder	hydroxypropyl cellulose	10.00	10.00	10.00	10.00
	Additive	lactose monohydrate	315.77	305.77	158.27	137.27
	Additive	microcrystalline cellulose	40.00	40.00	40.00	40.00
	Disintegrant	sodium starch glycolate	10.50(2.5%)	21.00(5.0%)	168.00(40.0%)	189.00(45.0%)
	Lubricant	magnesium stearate	3.60	3.60	3.60	3.60

[108]

[109] **Example 9**

[110] Double-layered tablets comprising pregelatinized starch as a disintegrant in an olmesartan medoxomil-containing layer were prepared by using the same procedures of Example 1 (except that the film-coating process was not performed), according to the components and amounts shown in Table 12. The amounts of the table

CLAIMS

Claim 1

A pharmaceutical composition having a single dosage form comprising a compartment comprising olmesartan medoxomil; and a compartment comprising rosuvastatin or its salt, wherein said compartments are formulated in a separate form,

wherein the compartment comprising olmesartan medoxomil comprises low substituted hydroxypropyl cellulose as a disintegrant; and wherein the low substituted hydroxypropyl cellulose is present in an amount ranging from 7.5 to 65 % by weight, based on the total weight of the compartment comprising olmesartan medoxomil, and

wherein the compartment comprising rosuvastatin or its salt comprises one or more disintegrant selected from the group consisting of crospovidone, low substituted hydroxypropyl cellulose, croscarmellose sodium, and carboxymethylcellulose calcium; and wherein the disintegrant is present in an amount ranging from 2 to 20 % by weight, based on the total weight of the compartment comprising rosuvastatin or its salt.

Claim 2

The pharmaceutical composition according to claim 1, having a double-layered tablet form, a tablet form consisting essentially of an inner core and an outer layer, or a pellet-containing capsule form.

Claim 3

The pharmaceutical composition according to claim 1, having a double-layered tablet form consisting essentially of a layer comprising rosuvastatin or its salt and a layer comprising olmesartan medoxomil.

Claim 4

The pharmaceutical composition according to claim 1, having a tablet form consisting essentially of an inner core comprising rosuvastatin or its salt and an outer layer comprising olmesartan medoxomil.

Claim 5

The pharmaceutical composition according to claim 1, having a capsule form filled with pellets comprising rosuvastatin or its salt and pellets comprising olmesartan medoxomil.

Claim 6

The pharmaceutical composition according to claim 1, wherein the compartment comprising olmesartan medoxomil comprises 10 to 60 % by weight of low substituted hydroxypropyl cellulose, based on the total weight of the compartment comprising olmesartan medoxomil.