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(54) **Title:** DISPERSIBLE TABLET COMPRISING COATED DRUG-CONTAINING PARTICLES AND METHOD FOR THE PREPARATION THEREOF

(57) **Abstract:** The present invention relates to a dispersible tablet comprising a plurality of a coated drug-containing particles and a method for preparing said dispersible tablet. The inventive dispersible tablet comprising (a) a plurality of a drug-containing particle having a coating layer on the surface thereof; (b) a binding agent for protecting the coating layer; and (c) a pharmaceutically acceptable excipient, is capable of: maintaining a suitable hardness to prevent from the breakage thereof during the packing, circulating or storing period; enhancing the patient compliance through masking the drug bitterness; and disintegrating and dispersing rapidly enough to be easily administered to young children or old people having difficulty in swallowing a conventional oral formulation.

DISPERSIBLE TABLET COMPRISING COATED DRUG-CONTAINING PARTICLES AND METHOD FOR THE PREPARATION THEREOF

Field of the Invention

The present invention relates to a dispersible tablet comprising coated drug-containing particles, having a suitable hardness for storage and transportation, enhanced patient compliance during oral administration through masking the drug bitterness, and outstanding disintegration rate and dispersibility characteristics in the oral cavity, and a method for preparing said dispersible tablet.

Background of the Invention

When a conventional oral tablet or capsule of a drug is administered, a large number of the patients, in particular, those having difficulty with swallowing, such as young children, old people, and patients with swallowing difficulty feel discomfort during swallowing.

Syrup formulations administered mainly to young children can alleviate such difficulty, but they have the disadvantages of inaccurate dose, instability during storage, the necessity of using an antiseptic, and others. In order to overcome such problems, there have been developed various type of dispersible tablets. Such dispersible tablets are required to have properties that satisfy rapid disintegration in the oral cavity, a proper hardness for storage and transportation, and an ability to mask the drug bitterness.

For example, U.S. Patent No. 5,776,492 discloses a tablet formulation prepared using microcrystalline cellulose and pharmaceutically acceptable excipients (without the use of a binding agent) which is capable of quickly dissolving after 25 to 30 sec, while maintaining a good hardness. Further, U.S. Patent No. 5,698,221 has disclosed a dispersible tablet formulated using a swelling clay and other excipients; and U.S. Patent No. 5,780,055, a suspensible

tablet prepared by wet-granulating microcrystalline cellulose, a disintegrant and a drug, and freeze-drying the resulting mixture.

However, the above formulations disclose only methods for the preparation of a dispersible tablet comprising mixing a drug with other excipients, while leaving the issue of the patient with regard to the drug bitterness unresolved compliance.

The present inventors have therefore endeavored to develop a dispersible tablet which effectively masks the drug bitterness, and have found that a dispersible tablet formulated using a plurality of a drug-containing particle having a coating layer comprising microcrystalline cellulose and a small amount of a binding agent is satisfactory in solving the above mentioned problems.

Summary of the Invention

Accordingly, it is an object of the present invention to provide a dispersible tablet maintaining a suitable hardness for storage and transportation stability, enhancing the patient compliance during administration through masking the drug bitterness, and having high disintegration rate and dispersibility so as to be easily administered to young children or old people having difficulty in swallowing oral formulation; and a method for preparing the same.

In accordance with one aspect of the present invention, there is provided a dispersible tablet comprising (a) a plurality of a drug-containing particle having a coating layer on the surface thereof; (b) a binding agent for protecting the coating layer; and (c) a pharmaceutically acceptable excipient.

In accordance with another aspect of the present invention, there is provided a method for preparing a dispersible tablet comprising the steps of: preparing drug-containing particles having a coating layer on the surface thereof; and mixing the drug-containing particles, binding agent for protecting the coating layer, and a pharmaceutically acceptable excipient, following by formulating the resulting mixture into a tablet.

Detailed Description of the Invention

The inventive dispersible tablet comprising coated drug-containing particles has the features that the coating layer masks the drug bitterness and the binding agent maintains the disintegration rate while protecting the coating layer from breaking.

The present invention may be advantageously used in the formulation of any of the known orally administered drugs having offensive taste, and representative examples of such drugs include but are not limited to roxithromycin, clarithromycin, azithromycin, erdosteine, famotidine, cefpodoxime proxetil, cefuroxime axetil, acetaminophen, and ivy extracts.

Further, in the present invention, the drug may be located in the insides or on the surfaces of the particle, the form of the drug-containing particle being not limited. Consequently, in one embodiment of the present invention, the drug-containing particle may take the form of a pellet formed by mixing the drug having offensive taste with a pellet-forming substance, or the form of an inert core coated by the drug. In another embodiment of the present invention, the drug-containing particle may be of a spherical form having a particle size raging from about 100 to about 1000 ㎛ in diameter, on the surface of which the coating layer for masking the drug bitterness can be easily formed.

When the amount of the drug-containing particle is excessive, it is difficult to attain a desired disintegration rate, and when too small, the size of the inventive formulation becomes too bulky. Therefore, the amount of the drug-containing particles may be 10 to 50 % by weight, preferably from 15 to 40 % by weight based on the total weight of the inventive dispersible tablet.

The pellet-forming substance may be one or more substances selected from the group consisting of microcrystalline cellulose, low-substituted hydroxypropylcellulose, chitin, and chitosan. The drug and the pellet-forming substance may be used in amounts corresponding to a weight ratio of 1:0.2 to 10. In case an inert core is need, it is preferably a spherical particle of sugar or microcrystalline cellulose having a particle size raging from 100 to 500 ㎛ in diameter.

In the present invention, the coated layer formed on the surfaces of the drug-containing particle may be used as a layer for masking offensive taste of the drug, which may comprise one or more coating substances selected from the group consisting of a water-insoluble polymer, a water-soluble polymer, and an enteric coating material. The water-insolube polymer may be an acrylic acid-based copolymer, polyvinylacetate or a cellulose derivative (e.g., ethyl cellulose and cellulose acetate), which may be employed in the form of an aqueous suspension, an aqueous milky liquid or a water-containing organic solution. Representative examples thereof may include an acrylic acid-based copolymer (e.g., Eudragit L30D-55, Eudragit FS30D, Eudragit RL30D, Eudragit RS30D and Eudragit NE30D, Deggusa; and acryl-Eze, Colorcon), a polyvinylacetate (e.g., Kollicoat SR 30D, BASF), and a cellulose derivative (e.g., Surelease, Colorcon); and Aquacoat ECD and Aquacoat CPD, FMC), which may be used separately or as a mixture with water.

Exemplary water-soluble polymers include one or more substances selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose, polyvinylalcohol, and polyvinylpyrrolidone.

The enteric coating material may be one of the known enteric polymers that dissolve in a solution having a pH value of 5 or higher, and representative examples thereof include a methacrylic acid copolymer (e.g., Eudragit L, S and FS30D, Deggusa), hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, and cellulose acetate phthalate.

In the present invention, the coating layer may further comprises a plasticizer in an amount ranging from 1 to 30 % by weight based on the weight of the coating material, as the need arises. Exemplary plasticizers of the present invention include polyethyleneglycol, propyleneglycol, triethylcitrate, triacetine, triacetine citrate, castor oil, dibutylsebacate, dibutyltartrate, diethylphthalate, and glycerine.

In order to prevent particle aggregation during the coating procedure of the drug-containing particles, the coating layer may further comprise a lubricant in an amount ranging from 10 to 50 % by weight based on the weight of the

coating substances. Representative examples of the lubricant used in the present invention include talc, silicon dioxide, and glycerylmonostearate.

The drug-containing particle may be coated with a coating solution containing the above coating substances by conventional methods such as top spraying, bottom spraying, and tangential spraying method using a conventional fluid coating machine. The coating process may be conducted under a conventional condition, e.g., at a temperature of 25 to 45℃, a spray rate of 5 to 30 mℓ/min, and a spray pressure of 1 to 3 bar, following by drying the coated particle at a temperature of 35 to 60℃ for 0.5 to 1 hrs to form the coated layer.

In the present invention, although the masking effect of the drug bitterness increases in a coating layer amount-dependent manner, when the amount is too much, both the production cost and the particle size increase. Accordingly, the amount of the coating layer is in the range from 2 to 40 % by weight, preferably 10 to 30 % by weight based on the total weight of the inventive dispersible tablet; and in the range from 10 to 100 % by weight, preferably 30 to 70 % by weight based on the weight of the drug-containing particles. Further, the amount of the drug-containing particle possessing the coating layer may be 5 to 70 % by weight, preferably 10 to 50 % by weight based on the total weight of the dispersible tablet in the present invention.

The dispersible tablet of the present invention comprises a binding agent for maintaining an effective disintegration rate while protecting the coating layer from breaking, and a pharmaceutically acceptable excipient.

The binding agent used in the present invention may be one of the known binding agents conventionally used in the field of pharmaceutical industries, which include synthetic polymers such as copovidone (e.g., Kolidon VA64, BASF), hydroxypropylcellulose (e.g., HPC-L, Nisso), polyvinylpyrrolidone (e.g., Kolidon K30, BASF), and hydroxypropylmethylcellulose (e.g., Pharmacoat 606, Shin-Etsu); natural gums such as arabic gum and xanthan gum; and a mixture thereof. The amount of the binding agent may be 0.1 to 8 % by weight, preferably 2 to 6 % by weight based on the total weight of the inventive dispersible tablet.

The pharmaceutically acceptable excipient used in the present invention may be one or more selected from the known pharmaceutically acceptable

excipients used in the field of pharmaceutical industries, which include a microcrystallinecellulose, a disintegrant, a flavoring agent, a sweetening agent, and a lubricant.

The microcrystalline cellulose used in the present invention may be one of the known microcrystalline celluloses which are currently available, irrespective of the particle size. Representative examples thereof include commercially available Avicel PH101 (FMC), Avicel PH102, and Avicel PH200, which may be employed in an amount ranging from 30 to 70 % by weight, preferably 40 to 60 % by weight based on the total weight of the inventive dispersible tablet. The disintegrant used in the present invention may be one or more substances selected from the group consisting of crospovidone (e.g., Kolidon CL, BASF), croscarmellose sodium (e.g., Ac-di-sol, FMC), sodium starch glycolate (e.g., Primojel, DMV), potassium carboxymethylcellulose, pregelatinated starch (e.g., Starch 1500, Colorcon) and low substituted hydroxypropylcellulose (e.g., L-HPC, Shin-Etsu), which may be employed in an amount ranging from 0.5 to 15 % by weight, preferably 3 to 10 % by weight based on the total weight of the inventive dispersible tablet.

The dispersible tablet of the present invention may be obtained by mixing the above coating-protecting substances, i.e., the binding agent and pharmaceutically acceptable excipient, with the coated drug-containing particles, and formulating the resulting mixture into a table having a hardness of 3 to 5 kp. The dispersible tablet of the present invention exhibits a disintegration time of 5 to 60 sec at a hardness of 3 to 5 kp.

The following Examples are intended to further illustrate the present invention without limiting its scope.

Example 1

(1) Preparation of drug-containing particles

650 g of an ivy leaf extract (Finzelberg, Germany), 19.5 g of hydroxypropylmethylcellulose and 19.5 g of talc were added with stirring to 2700 g of purified water, and the resulting mixture was coated on 611 g of microcrystalline cellulose pellets (CELLETS 200, Pharmatrans Sanaq Ag,

Germany) using a fluid coating machine under the condition described in Table 1.

Table 1

System name	Fluid Bed System	
Model No.	GPCG-1(Glau, Germany)	
Spray type	Bottom spray	
Temperature	Coating	Drying
	Inlet temperature: 55℃ Outlet temperature: 35-40℃ Product temperature: 35-40℃	Inlet temperature: 60-70 ℃ Outlet temperature: 45-55℃ Product temperature: 45-55℃
Spray rate	6 ml/min	
Spray pressure	2 bar	

(2) Coating with bitterness-masking layers

1200 g of the ivy leaf extract-containing pellets obtained in step (1) was coated with a bitterness-masking layer, made of the components shown in Table 2 under the condition described in Table 3.

Table 2

Component	Total content (g)	Solid content (g)
Eudragit L30D-55	1142.87	342.86
Triethylcitrate	34.29	34.29
Talc	102.86	102.86
Water	1119.99	0.0
Total weight	2400	480

Table 3

System name	Fluid Bed System	
Model No.	GPCG-1(Glau, Germany)	
Spray type	Bottom spray	
Temperature	coating	Drying
	Inlet temperature: 40-45℃ Outlet temperature: 25-30℃ Product temperature: 25-30℃	Inlet temperature: 50-60 ℃ Outlet temperature: 35-40℃ Product temperature: 35-40℃
Spray rate	5-10 ml/min	
Spray pressure	2.5 bar	

(3) Preparation of dispersible tablet

A mixture of 98 g of the pellets coated with the bitterness-masking layers obtained in step (2), 119.07 g of microcrystallinecellulose, 7.35 g of copovidone, 7.35 g of croscarmellose sodium, 7.35 g of crospovidone, 2.45 g of strawberry flavor cotton, 0.98 g of sucralose and 2.45 g of sodiumstearylfumarate was formulated into tablets using a 8 mm diameter round punch to obtain the inventive dispersible tablets having a hardness of 3.5 to 4.0 kp.

Example 2

(1) Preparation of drug-containing pellets

350 g of roxithromycin and 350 g of microcrystallinecellulose were mixed using a centrifugal fluid-bed granulator (GPCG-1, Glatt, Germany) for 1 min, and 700 g of water was spray to the mixture under the condition described in Table 4 to obtain pellets, which were mostly spherical particles having a particle size of 0.4 to 0.5 mm in diameter.

Table 4

System name	Fluid Bed System	
Model No.	GPCG-1(Glau, Germany)	
Spray type	Tangential spray	
Temperature	Granulating	Drying
	Inlet temperature: 30℃ Outlet temperature: 15-25℃ Product temperature: 15-25℃	Inlet temperature: 60-70 ℃ Outlet temperature: 35-40℃ Product temperature: 35-40℃
Spray rate	10-30 ml/min	
Spray pressure	1-2 bar	
Rotational speed	300-700 rpm	

(2) Coating with bitterness-masking layers

700 g of the roxithromycin-containing pellets obtained in step (1) was coated with a bitterness-masking layer formed using the ingredients shown in Table 5 under the condition described in Table 6.

Table 5

Component	Total content (g)	Solid content (g)
Eudragit L30D-55	66.67	20.00
Triethylcitrate	2.00	2.00
Talc	6.00	6.00
Water	65.33	0.00
Total weight	140.00	28.00

Table 6

System name	Fluid Bed System	
Model No.	GPCG-1(Glau, Germany)	
Spray type	Bottom spray	
Temperature	Coating	Drying
	Inlet temperature: 40-45℃ Outlet temperature: 25-30℃ Product temperature: 25-30℃	Inlet temperature: 50-60 ℃ Outlet temperature: 35-40℃ Product temperature: 35-40℃
Spray rate	5-10 ml/min	
Spray pressure	2.5 bar	

(3) Preparation of dispersible tablet

A mixture of 98 g of the pellets coated with the bitterness-masking layers obtained in step (2), 114.17 g of microcrystallinecellulose, 12.25 g of copovidone, 14.7 g of crospovidone, 2.45 g of strawberry flavor cotton, 0.98 g of sucralose and 2.45 g of sodiumstearylfumarate was formulated into tablets using a 8 mm diameter round punch to obtain the inventive dispersible tablets having a hardness of 3.5 to 4.0 kp.

Example 3

(1) Preparation of drug-containing pellets

350 g of clarithromycin and 350 g of microcrystallinecellulose were mixed using a centrifugal fluid-bed granulator (GPCG-1, Glatt, Germany), and the mixture was mixed for 1 min, 600 g of water was spray to the mixture under the same condition described in Example 2 (Table 4) to obtain pellets, which were mostly spherical particles having a particle size of 0.2 to 0.4 mm in diameter.

(2) Coating with bitterness-masking layers

700 g of the clarithromycin-containing pellets obtained in step (1) was coated with a bitterness-masking layer formed using the ingredients shown in Table 7 under the condition described in Table 3.

Table 7

Component	Total content (g)	Solid content (g)
Eudragit L30D-55	83.33	25.00
Triethylcitrate	2.50	2.50
Talc	7.50	7.50
Water	81.67	0.00
Total weight	175.00	35.00

(3) Preparation of dispersible tablet

A mixture of 98 g of the pellets coated with the bitterness-masking layers obtained in step (2), 116.62 g of microcrystallinecellulose, 4.9 g of hydroxypropylcellulose, 19.6 g of crospovidone, 2.45 g of strawberry flavor cotton, 0.98 g of sucralose and 2.45 g of sodiumstearylfumarate was formulated into tablets using a 8 mm diameter round punch to obtain the inventive dispersible tablets having a hardness of 3.5 to 4.0 kp.

Examples 4 to 6

The coated pellets obtained by repeating the procedures of steps (1) and (2) of Example 1 were mixed with the components listed in Table 8 according to the amounts described in Table 8 to obtain the dispersible tablets of Examples 4 to 6, which each have a particle size of 8 mm in diameter and a hardness of 3 to 4 kp. The dispersible tablets of Examples 4 to 6 each comprised binding agents in an amount ranging from 1.0 to 3.0 % by weight based on the total weight thereof.

Table 8

Component (g)	Example 4	Example 5	Example 6
Bitterness-masked pellets	40.00	40.00	40.00
Microcrystalline cellulose	49.60	48.60	47.60
Copovidone	1.00	2.00	3.00
Croscarmellose sodium	3.00	3.00	3.00
Crospovidone	3.00	3.00	3.00
Strawberry flavor cotton	2.00	2.00	2.00
Sucralose	0.40	0.40	0.40
Sodiumstearylfumarate	1.00	1.00	1.00
Total weight	100.00	100.00	100.00

Examples 7 and 8 and Comparative Examples 1 and 2

The coated pellets obtained by repeating the procedures of steps (1) and (2) of Example 1 were mixed with the components shown in Table 9 to obtain dispersible tablets of Examples 7 and 8 and Comparative Examples 1 and 2, which each have a particle size of 8 mm in diameter and a hardness of 3 to 4 kp. The dispersible tablets of Examples 7 to 8 each comprised binding agents in an amount ranging from 6.0 to 8.0 % by weight based on the total weight thereof; Comparative Example 1, binding agents in an amount of 10 % by weight; and Comparative Example 2, no binding agents.

Table 9

Component (g)	Example 7	Example 8	Comparative Example 1	Comparative Example 2
Bitterness-masked pellets	40.00	40.00	40.00	40.00
Microcrystalline cellulose	44.60	42.60	40.60	50.60
Copovidone	6.00	8.00	10.00	0.00
Croscarmellose sodium	3.00	3.00	3.00	3.00
Crospovidone	3.00	3.00	3.00	3.00
Strawberry flavor cotton	2.00	2.00	2.00	2.00
Sucralose	0.40	0.40	0.40	0.40
Sodiumstearylfumarate	1.00	1.00	1.00	1.00
Total weight	100.00	100.00	100.00	100.00

Test Example 1: Dissolution test

Each of the 10 dispersible tablets prepared in Examples 4 to 8 and Comparative Examples 1 and 2 was subjected to a drug dissolution test according to the first method described in Korea Pharmacopoeia. The dissolution test was conducted using 900 ml of water as the eluent at a rotational speed of 100 rpm, and 10 min after starting the test, 3 ml of each test solution was taken, filtered, and analyzed by HPLC under the following condition. The results are shown in Table 10.

- Column: Kromasil 150×4.6 mm, 5 um
- Detector: UV 205 nm
- Flow rate: 1 ㎖/min
- Injection volumn: 20 μL
- Temperature of column: 40℃
- Mobile phase: A - 0.001 mol/L aqueous phosphoric acid
  B - 10 ml of 0.1 mol/L aqueous phosphoric acid + adjusting with 1000 ml of acetonitrile

Table 10

Dispersible tablet	Dissolution rate (%)
Example 4	35.15
Example 5	27.93
Example 6	22.99
Example 7	19.56
Example 8	18.11
Comparative Example 1	16.74
Comparative Example 2	44.23

Table 10 shows that the dispersible tablets of Examples 4 to 8 comprising binding agent, exhibited lower dissolution rates as compared to that of Comparative Example 2 comprising no binding agent, and that the dissolution rate decreased as the amount of the binding agent increased. The dispersible tablet of Comparative Example 1 which comprises a large quantity of the binding agent exhibited a significantly low dissolution rate. This suggest

that the binding agent in the inventive dispersible tablet plays the role of protecting the coating layer from breaking during the tablet formulation step.

Test Example 2: Disintegration test

The dispersible tablets prepared in Examples 4 to 8 and Comparative Examples 1 and 2 were each subjected to a drug disintegration test according to the method described in Korea Pharmacopoeia. The results are shown in Table 11.

Table 11

Test sample	Example 4	Example 5	Example 6	Example 7	Example 8	Comparative Example 1	Comparative Example 2
1	9	10	12	23	55	144	7
2	8	9	12	22	72	139	8
3	10	10	13	21	56	180	7
4	8	11	12	21	50	160	7
5	9	11	10	23	68	150	6
6	9	10	13	23	60	178	7
Average	9	10	12	22	60	159	7

As shown in Table 11, the dispersible tablet prepared in Comparative Example 1 comprising 10% binding agent, exhibited the longest disintegration time (159 sec), and the dispersible tablet prepared in Comparative Example 2 comprising no binding agent, exhibited the shortest disintegration time (7 sec). Meanwhile, the dispersible tablets of Examples 4 to 8 exhibited satisfactory disintegration times ranging from 9 to 60 sec.

While the invention has been described with respect to the above specific embodiments, it should be recognized that various modifications and changes may be made to the invention by those skilled in the art which also fall within the scope of the invention as defined by the appended claims.

What is claimed is:

1. A dispersible tablet comprising
(a) a plurality of a drug-containing particle having a coating layer on the surface thereof;
(b) a binding agent for protecting the coating layer; and
(c) a pharmaceutically acceptable excipient.

2. The dispersible tablet of claim 1, wherein the coating layer comprises at least one selected from the group consisting of a water-insoluble polymer, a water-soluble polymer, and an enteric coating material.

3. The dispersible tablet of claim 2, wherein the water-insoluble polymer is selected from the group consisting of an acrylic acid-based copolymer, a polyvinylacetate, and a cellulose derivative.

4. The dispersible tablet of claim 2, wherein the water-soluble polymer is selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose, methylcellulose, polyvinylalcohol, and polyvinylpyrrolidone.

5. The dispersible tablet of claim 2, wherein the enteric coating material is an enteric polymer soluble in a solution having a pH value higher than 5.

6. The dispersible tablet of claim 5, wherein the enteric polymer is selected from the group consisting of a methacrylic acid-copolymer, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, and cellulose acetatephthalate.

7. The dispersible tablet of claim 1, wherein the binding agent is selected from the group consisting of a synthetic copolymer which is copovidone, hydroxypropylcellulose, polyvinylpyrrolidone or hydroxypropylmethylcellulose, a natural gum which is arabic gum or xanthan gum, and a mixture thereof.

8. The dispersible tablet of claim 1, wherein the amount of the drug-containing particle is 5 to 70 % by weight based on the total weight of the dispersible tablet.

9. The dispersible tablet of claim 1, wherein the amount of the coating layer is 2 to 40 % by weight based on the total weight of the dispersible tablet.

10. The dispersible tablet of claim 1, wherein the coating layer further comprises a plasticizer in an amount ranging from 1 to 30 % by weight based on the weight thereof.

11. The dispersible tablet of claim 1, wherein the amount of the binding agent is 0.1 to 8 % by weight based on the total weight of the dispersible tablet.

12. The dispersible tablet of claim 1, wherein the pharmaceutically acceptable excipient is selected from the group consisting of microcrystallinecellulose, a disintegrant, a flavoring agent, a sweetening agent and a lubricant.

13. The dispersible tablet of claim 12, wherein the disintegrant is selected from the group consisting of crospovidone, croscarmellose sodium, sodium starch glycolate, potassium carboxymethylcellulose, pregelatinated starch and low substituted hydroxypropylcellulose.

14. The dispersible tablet of claim 13, wherein the amount of the disintegrant is 0.5 to 15 % by weight based on the total weight of the dispersible tablet.

15. The dispersible tablet of claim 12, wherein the amount of the microcrystallinecellulose is 30 to 70 % by weight based on the total weight of the dispersible tablet.

16. The dispersible tablet of claim 1, which comprises a plurality of a drug-containing particle having a coating layer in an amount of 5 to 70 % by weight, the binding agent in an amount of 2 to 6 % by weight, and the pharmaceutically acceptable excipient in an amount of the balance, based on the total weight thereof.

17. The dispersible tablet of claim 1, which has a disintegration time of 5 to 60 sec.

18. A method for preparing a dispersible tablet comprising the steps of:
preparing drug-containing particles having a coating layer on the surface thereof; and
mixing the drug-containing particles, binding agent for protecting the coating layer, and a pharmaceutically acceptable excipient, following by formulating the resulting mixture into a tablet.