DESCRIPTION

ORAL FAST-DISINTEGRATING TABLET

FIELD OF THE INVENTION

The present invention relates to an oral fast-disintegrating tablet that rapidly disintegrates in the presence of the saliva in the oral cavity or of a small amount of water, and more specifically to an oral fast-disintegrating tablet that contains a useful bacterium and that has excellent long-term storage stability.

BACKGROUND ART

In the human gastrointestinal tract, intestinal bacteria are present, and recently as many as 100 trillion intestinal bacteria are said to be present in the entire gastrointestinal tract, forming the intestinal bacterial flora. The intestinal bacteria include the useful or good bacteria such as Bifidobacteria and lactic acid bacteria and the bad bacteria such as Escherichia coli and Welch bacteria, and the balance of these bacteria exerts useful effect on humans. It has come to be known recently that the disturbance of this balance may affect the decomposition, digestion and absorption of nutrients, immunity, infection protection, aging and the like, and that the maintenance of the balance of the intestinal bacterial flora is deeply involved in human health. The disturbance of the intestinal bacterial flora not only causes conditions often encountered by modern people such as stress, disorderly eating habits, fatigue, and lack of sleep but aging may also cause the disturbance of the intestinal bacterial flora, which are common to everyone.

In order to improve the disturbance of the intestinal bacterial flora, live bacterial formulations such as Bifidobacteria have been presented to patients as ethical drugs, OTC drugs, or supplements in the form of powders, tablets, capsules and the like.

The development of oral disintegrating tablets are being sought after as drugs that can be taken without any limitation on the site of drug taking or without water by those having a reduced deglutition ability such as elderly people and small children or even normal adults, and in fact some of such drugs have already been developed. In references disclosing such drugs, there are known (1) a tablet produced by a method (see Japanese Unexamined Patent Publication (Kokai) No. 5-271054) in which a mixture containing a drug, a sugar and water at an amount sufficient to wet the surface of the sugar is compressed into tablets, and then dried, (2) a tablet produced by a method (see Japanese Unexamined Patent Publication (Kokai) No. 11-12161) in which a drug, a water-soluble excipient and an amorphous sugar are compression-molded and subjected to aging, (3) a tablet (Kokai (see Japanese Unexamined Patent Publication) No. 2000-273038) which comprises a drug, lactose, a crystalline cellulose and light anhydrous silicic acid at a given ratio and furthermore a disintegrant such as crosspovidone.

Furthermore, (4) in "Application of crystalline cellulose/light anhydrous silicic acid (trade name: PROSOLV) in pharmaceutical drugs (2)" in the 124th Annual Meeting of The Pharmaceutical Society of Japan, the application of crystalline cellulose/light anhydrous silicic acid into live bacterial formulations has been mentioned, and it has been indicated that crystalline cellulose/light anhydrous silicic acid can be made into a dosage form at a low-pressure tablet making, and therefore can reduce the loss of live bacteria during tablet making and that the disintegrating time of this tablet was about 1.5-2 minutes.

However, these known references do not explicitly indicate oral disintegrating tablets that contain useful bacteria. Thus, the tablet in (1) cannot be applied to useful bacteria that are unstable to moisture since a wet

mixture is made into tablets, in the tablet in (2), naked tablets must undergo aging under the condition of a given temperature and humidity, which has a drawback of leading to the increased drying loss of the tablet and the reduced storage stability of useful bacteria. The tablet in (3) is different from that of the present invention in the composition of the tablet, and crystalline cellulose/light anhydrous silicic acid used in the present invention have not been used and besides no mention has been made on the useful bacterium formulation or its storage stability. Also, (4) mentions an example in which crystalline cellulose/light anhydrous silicic acid were applied in useful bacteria such as Bifidobacteria, and describes that the loss of the number of live bacteria during tablet making can be reduced. However, (4) has no description on the storage stability or the fast-disintegrating property of the live bacterial formulation obtained.

DISCLOSURE OF THE INVENTION

Thus, it is an object of the present invention to develop an oral fast-disintegrating tablet, in which useful bacteria are rapidly disintegrated in the oral cavity, which has an appropriate strength, which can be produced by a very simple method using a common compression-molding machine, and which has an excellent long-term storage stability of useful bacteria contained.

In accordance with the present invention, there is provided an oral fast-disintegrating tablet which has a useful bacterium, crystalline cellulose/light anhydrous silicic acid and a starch-containing saccharide, and a moisture content of 3.2% by weight or less.

The aspects of the present invention are described below.

(1) The above oral fast-disintegrating tablet in which the useful bacterium is a Bifidobacterium or a lactic acid bacterium.

(2) The above oral fast-disintegrating tablet in

which the useful bacterium is a Bifidobacterium.

(3) The above oral fast-disintegrating tablet comprising 35-70 parts by weight of crystalline cellulose/light anhydrous silicic acid relative to 100 parts by weight of the tablet.

(4) The above oral fast-disintegrating tablet comprising 25-60 parts by weight of a starch-containing saccharide relative to 100 parts by weight of the tablet.

(5) The above oral fast-disintegrating tablet comprising 40-70 parts by weight of crystalline cellulose/light anhydrous silicic acid and 30-60 parts by weight of a starch-containing saccharide relative to 100 parts by weight of the tablet.

(6) The above oral fast-disintegrating tablet in which the tablet hardness is 30N-60N.

(7) A method of producing an oral fast-disintegrating tablet said method comprising compression-molding a mixed powder of a useful bacterium, crystalline cellulose/light anhydrous silicic acid and a starch-containing saccharide in the dry form to obtain a tablet with a moisture content of 3.2% by weight or less.

BEST MODE FOR CARRYING OUT THE INVENTION

After intensive and extensive research in order to solve the above problems, the present inventors have found that a blend of a useful bacterium with crystalline cellulose/light anhydrous silicic acid and a starch-containing saccharide can be made into a tablet at a relatively low tableting pressure by an ordinary tableting machine, and therefore an oral fast-disintegrating tablet can be obtained that can disintegrate rapidly in the oral cavity, has an appropriate hardness, a low rate of killing a useful bacterium during tablet making, and an excellent long-term storage stability. The present invention was accomplished based on such findings with further research.

The useful bacterium for use in the present

invention may be any bacterium that is useful for the digestion activity of humans. There can be mentioned Bifidobacteria (*Bifidobacterium longum*, *Bifidobacterium infantis*, *Bifidobacterium bifidum*, *Bifidobacterium breve* etc.), lactic acid bacteria (*Lactobacillus casei*, *Lactobacillus gasseri*, *Lactobacillus acidophilus*, *Streptococcus faecalis*, *Streptococcus thermophilus* etc.) and the like. Preferably there can be mentioned a Bifidobacterium, specifically *Bifidobacterium longum*, *Bifidobacterium infantis*, etc. Two or more useful bacteria may be blended as appropriate.

The useful bacterium for use in the present invention may be used in the form of a live bacterial powder, a lyophilized product etc. The amount blended may be 0.03-30 parts by weight relative to 100 parts by weight of the tablet, and for a better molding property, 0.1-20 parts by weight, specifically 0.5-10 parts by weight may be preferred. The number of bacteria blended may not be specifically limited, and considering the effectiveness, the number of live bacteria is 10^5-10^{10} cells/tablet, and more preferably 10^6-10^9 cells/tablet.

The useful bacterium for use in the present invention may be combined with a pharmaceutical drug that does not badly affect the useful bacterium and another active ingredient such as a health food.

The crystalline cellulose/light anhydrous silicic acid for use in the present invention is an excipient that is produced by mixing crystalline cellulose and a small amount of light anhydrous silicic acid in the slurry form and then by spray-drying it, and the method of production is described in Japanese Patent No. 3300364. This may be "PROSOLV" (registered trademark) commercially available from JRS PHARMA. Crystalline cellulose/light anhydrous silicic acid may be used at 35-70 parts by weight, preferably 40-70 parts by weight relative to 100 parts by weight of the tablet.

The starch-containing saccharide for use in the

present invention may be any saccharide that contains at least starch, or may be starch alone, or it may be a mere blend of starch and one or more of other saccharides, or it may be a granulated product thereof. According to the present invention, as a starch-containing saccharide, the one comprising 40 parts by weight or more of starch, preferably 70 parts by weight or more of starch may usually be used. The method of granulating the starch-containing saccharide is not specifically limited, and there can be mentioned spray drying, agitation granulation, fluidized bed granulation, extrusion granulation, and the like. The origin of starch is not specifically limited. There can be mentioned, for example, maize starch, wheat starch, potato starch, and the like. As other starches, there can be mentioned lactose, lactulose, sucrose, maltose, powder candy, dextrose, fructose, maltitol, mannitol, sorbitol, xylitol, erythritol and the like.

The amount used of the starch-containing saccharide may vary with the content of the starch contained in the starch-containing saccharide, and usually 25-60 parts by weight may be used relative to 100 parts by weight of the tablet. For example, when a starch/lactose granulated mixture containing starch and lactose at a ratio of about 7:3 is used as the starch-containing saccharide, it is used at about 25-60 parts by weight, preferably 30-60 parts by weight relative to 100 parts by weight of the tablet.

The tablet of the present invention may be optionally blended with various additives commonly used in tablet production. Such an additive may be used alone or in combination at suitable ratios. As the additive, there can be mentioned, for example, a disintegrant, a binder, an acidifying agent, a foaming agent, an artificial sweetener, a corrigent, a perfume, a fluidizer, a lubricant, a coloring agent, a stabilizing agent, and an excipient.

Generally, the oral fast-disintegrating tablet is blended with a disintegrant in order to impart the desired disintegrating property. As such a disintegrant, there can be mentioned crosspovidone, low substituted hydroxypropylcellulose, carmellose calcium, crosscarmellose sodium, carboxymethyl starch sodium and the like. Among them, crosspovidone is most often used. However, the oral fast-disintegrating tablet of the present invention can rapidly disintegrate in the oral cavity without blending a disintegrant.

The production of the oral fast-disintegrating tablet of the present invention may be carried out by compression-molding a mixture of a useful bacterium, crystalline cellulose/light anhydrous silicic acid and a starch-containing saccharide and, as desired, another additive in the dry form to obtain a tablet with a moisture content of 3.2% by weight or less. According to the present invention, the particle size of the additive such as a useful bacterium is not specifically limited, but smaller particles may lead to products which facilitates in drug taking. Another additive, as desired, excluding the useful bacterium, may be one that was dried after wet granulation. In this case, after mixing crystalline cellulose/light anhydrous silicic acid, a starch-containing saccharide etc., the process of spray drying, agitation granulation, fluidized bed granulation, extrusion granulation, and the like may be carried out. For compression molding, an instrument generally used for tablet molding may be used, such as a rotary tableting machine.

According to the present invention, in order to prevent the killing of the useful bacterium during tablet making, it is preferred to set the tableting pressure relatively low, and besides to make tablets at a hardness that does not break the tablet. Generally the tableting pressure of about 1 ton or less may be preferred.

The oral fast-disintegrating tablet of the present

invention thus obtained has a disintegrating property in the oral cavity and has a suitable tablet hardness. The disintegrating time in the oral cavity is generally 5-50 seconds, preferably 5-40 seconds, more preferably 5-30 seconds. Also, the tablet hardness is such that does not break the tablet during the distribution process, and that gives a tablet of which disintegrating time is short, and the tablet may preferably have a hardness of about 30N-60N, more preferably about 30N-50N.

The moisture content of the tablet may significantly affect the long-term storage stability of the useful bacterium. Thus, the moisture content of the oral fast-disintegrating tablet must be as small as possible. According to the present invention, the moisture content is maintained at 3.2% by weight or less, preferably 2.5% by weight or less. For the storage of the tablet, it is usually placed in a glass vial enclosing a desiccant. SP packaging etc. that completely seal the tablet in an aluminum package is preferred.

As a method of taking the drug, there can be mentioned (1) a method of taking the tablet in the mouth, disintegrating the tablet with the saliva in the oral cavity without water, and taking it as it is, (2) a method of taking the tablet in the mouth, also a small amount of water, and disintegrating the tablet in the oral cavity and taking it, (3) a method of taking the tablet together with water in the mouth, and taking it as it is, or (4) a method of first disintegrating the tablet in water and then taking it. The oral fast-disintegrating tablet of the present invention may be used specifically effectively (a) when it is often taken without water, (b) when it is taken by a patient who has difficulty in swallowing a tablet, (c) when a number of drugs must be taken at the same time, or (d) when it is taken by an elderly or a child who has a risk of being choked with a tablet.

EXAMPLES

The present invention will now be explained in more detail with reference to Examples and Comparative Examples, but it should be noted that the present invention is not limited to them in any way. The physical properties (hardness, disintegrating time, and stability testing of the useful bacterium) of the tablet were measured by the following test methods.

The Bifidobacterial powder used in the following Examples and Comparative Examples is a powder obtained by culturing *Bifidobacterium longum* and *Bifidobacterium infantis* and then lyophilizing them, and contains about 1 $\times 10^{10}$ cells/g of live bacteria.

(1) Hardness test

It was measured using a tablet durometer (FUJIWARA). Testing was repeated ten times, and the mean value was indicated.

(2) Disintegration test

It was evaluated by the disintegration test according to the Japanese Pharmacopoeia. The test used a disintegration tester (Toyama Sangyo Co., Ltd.), and measured without an accessory plate. The test solution used was water (37°C). The test was performed on six tablets, and the mean value was indicated.

(3) Measurement of the disintegrating time in the oral cavity

The time until the tablet becomes disintegrated with the saliva alone in the oral cavity was measured. The test was performed for three times, and the mean value was indicated.

(4) Storage stability test

After packaging each tablet in an aluminum package, it was stored at a temperature of 40°C and a relative humidity of 75% for one week or two weeks. The reduction in the number of microorganisms during that time was measured using a medium (horse defibrinated blood was added) by a plating method. Based on the numbers of live

bacteria before and after storage, the survival rate of Bifidobacteria was determined.

Examples 1-3

After a Bifidobacterial powder, crystalline cellulose/light anhydrous silicic acid (PROSOLV 90, manufactured by JRS PHARMA), a starch-containing saccharide (one of maize starch, a maize starch-granulated product, and a maize starch/lactose granulated mixture (maize starch : lactose (weight ratio) = 70:29)) were mixed, Mg stearate was added thereto and remixed to prepare a powder for tablet making. Using a rotary tablet machine (PICCORA, manufactured by RIVA. S.A.), tablets were made using a sugar-coated pestle to 280 mg/tablet, 9 mmϕ, and a hardness of about 40N. For the tablet obtained, a disintegrating test and the measurement of the disintegrating time in the oral cavity were carried out. The results are shown in Table 1.

Table 1

		Ex. 1	Ex. 2	Ex. 3
Amount blended	Bifidobacterium powder	10	10	10
	Crystalline cellulose/light anhydrous silicic acid	139	139	139
	Maize starch	131	-	-
	Granulated maize starch	-	131	-
	Granulated mixture of maize starch and lactose	-	-	131
	Mg stearate	0.3	0.3	0.3
Tablet physical properties	Hardness (N)	39.7	38.1	40.2
	Disintegrating time (seconds)	23	17	17
	Measurement of the disintegrating time in the oral cavity (seconds)	9	20	24

The results in Table 1 indicate that the oral fast-disintegrating tablet of the present invention has an appropriate hardness, and exhibits an excellent disintegrating property in the disintegrating test and the oral disintegrating test.

Example 4 and Comparative Example 1

After a Bifidobacterial powder, crystalline cellulose/light anhydrous silicic acid (PROSOLV 90, manufactured by JRS PHARMA), a maize starch-granulated mixture were mixed, Mg stearate was added thereto and remixed to prepare a powder for tablet making. Using a rotary tablet machine (PICCORA, manufactured by RIVA. S.A.), tablets were made using a sugar-coated pestle to 280 mg/tablet, 9 mmϕ, and a hardness of about 40N. For the tablet obtained, a storage stability test (storage period: two weeks) was carried out. The results are shown in Table 2.

Table 2

		Ex. 4	Comp. Ex. 1
Amount blended	Bifidobacterium powder	10	10
	Crystalline cellulose/light anhydrous silicic acid	139	270
	Granulated mixture of maize starch and lactose	131	-
	Mg stearate	0.3	0.3
Tablet physical properties	Drying loss (% by weight)	2.2	2.2
	Hardness (N)	45.1	40.4
	Disintegrating time (seconds)	17	71
	Measurement of the disintegrating time in the oral cavity (seconds)	23	9
	Storage stability test (Survival rate) (%)	16	4

The results in Table 2 indicate that the oral fast-disintegrating tablet of the present invention exhibits an excellent disintegrating property in the disintegrating test, and also has an excellent survival rate of Bifidobacterium. In contrast, for the tablet containing no starch-containing saccharide (a maize starch/lactose granulated mixture), the disintegrating time becomes longer since small pieces of the tablet remain in the basket, and the survival rate becomes low.

Comparative Examples 2 and 3

After a Bifidobacterial powder, crystalline

cellulose (Avicel PH101, Asahi Kasei Corporation), mannitol, lactose, light anhydrous silicic acid and crosspovidone (Kollidon CL, manufactured by BASF AG) were mixed, Mg stearate was added thereto and remixed to prepare a powder for tablet making. Using a rotary tablet machine (PICCORA, manufactured by RIVA. S.A.), tablets were made using a sugar-coated pestle to 280 mg/tablet, 9 mmϕ, and a hardness of about 40N. For the tablet obtained, a disintegration test, the measurement of the disintegrating time in the oral cavity, and a storage stability test (storage period: one week) were carried out. The results are shown in Table 3.

Table 3

		Ex. 1	Comp. Ex. 2	Comp. Ex. 3
Amount blended	Bifidobacterium powder	10	10	10
	Crystalline cellulose/light anhydrous silicic acid	139	-	-
	Maize starch	131	-	-
	Crystalline cellulose	-	108	81
	Mannitol	-	161	-
	Lactose	-	-	162
	Light anhydrous silicic acid	-	-	8.1
	Crosspovidone	-	-	16.2
	Mg stearate	0.3	0.84	2.7
Tablet physical properties	Drying loss (% by weight)	2.5		
	Hardness (N)	39.7	43.7	39.0
	Disintegrating time (seconds)	23	14	14
	Measurement of the disintegrating time in the oral cavity (seconds)	9	15	16
	Storage stability test (Survival rate) (%)	57	0.8	<0.3

The results in Table 3 indicate that the oral fast-disintegrating tablet of the present invention has an appropriate hardness, and exhibits an excellent disintegrating property in the oral cavity, and also has an excellent survival rate of Bifidobacterium. In contrast, for the tablet produced without blending crystalline cellulose/light anhydrous silicic acid or

starch has a significantly low storage stability.

Example 5 and Comparative Examples 4 and 5

After a Bifidobacterial powder, crystalline cellulose/light anhydrous silicic acid (PROSOLV 90, manufactured by JRS PHARMA), a maize starch, a maize starch/lactose granulated mixture were mixed, Mg stearate was added thereto and remixed to prepare a powder for tablet making. Using a rotary tablet machine (PICCORA, manufactured by RIVA. S.A.), tablets were made using a sugar-coated pestle to 280 mg/tablet, 9 mmϕ, and a hardness of about 30N-40N. The tablet with a drying loss of 2.2-7.3% by weight was used. For the tablet obtained, a disintegration test, the measurement of the disintegrating time in the oral cavity, and a storage stability test (storage period: one week) were carried out. The results are shown in Table 4.

Table 4

		Ex.1	Ex.3	Ex.5	Comp. Ex.4	Comp. Ex.5
Amount blended	Bifidobacterium powder	10	10	10	10	10
	Crystalline cellulose/light anhydrous silicic acid	139	139	139	139	139
	Maize starch	131	-	-	131	131
	Granulated mixture of maize starch and lactose	-	131	131	-	-
	Mg stearate	0.3	0.3	0.3	0.3	0.3
Tablet physical properties	Drying loss (% by weight)	2.5	2.2	3.2	6.1	7.3
	Hardness (N)	39.7	40.2	39.0	32.9	42.1
	Disintegrating time (seconds)	23	17	18	17	15
	Measurement of the disintegrating time in the oral cavity (seconds)	9	24	21	9	9
	Storage stability test (Survival rate) (%)	57	45	32	4	<0.2

The results in Table 4 indicate that in order to

obtain a tablet that, while maintaining an appropriate hardness, exhibits an excellent disintegrating property in the oral cavity, and besides an excellent survival rate, the moisture of the tablet (the drying loss) may preferably be 3.2% by weight or less.

Examples 6-9 and Comparative Example 6

After a Bifidobacterial powder, crystalline cellulose/light anhydrous silicic acid (PROSOLV 90, manufactured by JRS PHARMA), and a maize starch/lactose granulated mixture were mixed, Mg stearate was added thereto and remixed to prepare a powder for tablet making. Using a rotary tablet machine (PICCORA, manufactured by RIVA. S.A.), tablets were made using a sugar-coated pestle to 280 mg/tablet, 9 mmϕ, and a hardness of about 30, 40, 50, and 60N. For the tablet obtained, a disintegration test and measurement of the disintegrating time in the oral cavity were carried out. The results are shown in Table 5.

Table 5

		Ex.6	Ex.7	Ex.8	Ex.9	Comp. Ex.6
Amount blended	Bifidobacterium powder	10	10	10	10	10
	Crystalline cellulose/light anhydrous silicic acid	139	139	139	139	139
	Granulated mixture of maize starch and lactose	131	131	131	131	131
	Mg stearate	0.3	0.3	0.3	0.3	0.3
Tablet physical properties	Hardness (N)	32.2	41.9	52.3	61.8	82.9
	Disintegrating time (seconds)	19	17	17	22	97
	Measurement of the disintegrating time in the oral cavity (seconds)	18	24	30	43	74

The results in Table 5 indicate that in order to have a disintegrating time of about 40 seconds or less, the hardness of the oral fast-disintegrating tablet of

the present invention may preferably be about 30N or more and about 60N or less.

Examples 10-12 and Comparative Examples 7-9

After a Bifidobacterial powder, crystalline cellulose/light anhydrous silicic acid (PROSOLV 90, manufactured by JRS PHARMA), and a maize starch/lactose granulated mixture were mixed, Mg stearate was added thereto and remixed to prepare a powder for tablet making. Using a rotary tablet machine (PICCORA, manufactured by RIVA. S.A.), tablets were made using a sugar-coated pestle to 280 mg/tablet, 9 mmϕ, and a hardness of about 30N-40N. The tablet in which the amount blended of the crystalline cellulose/light anhydrous silicic acid in the tablet is about 9-87 parts by weight, and also the maize starch/lactose granulated mixture is about 9-87 parts by weight was produced. For the tablet obtained, a disintegration test, the measurement of the disintegrating time in the oral cavity, and a storage stability test were carried out. The results are shown in Table 6.

Table 6

		Ex.10	Ex.11	Ex.12	Comp. Ex.7	Comp. Ex.8	Comp. Ex.9
Amount blended	Bifidobacterium powder	10	10	10	10	10	10
	Crystalline cellulose/light anhydrous silicic acid	108	135	189	27	81	243
	Granulated mixture of maize starch and lactose	162	135	81	243	189	27
	Mg stearate	0.3	0.3	0.3	0.3	0.3	0.3
Tablet physical properties	Hardness (N)	35.9	38.2	35.6	31.2	36.0	35.6
	Disintegrating time (seconds)	23	15	24	179	66	57
	Disintegrating time in the oral cavity (seconds)	38	26	13	80	50	13
	Storage stability (Survival rate) (%)	-	21	14	24	21	7

The results in Table 6 indicate that in order to obtain a disintegrating time of about 40 seconds or less, the amount blended of the crystalline cellulose/light anhydrous silicic acid in the tablet may preferably be about 35-70 parts by weight, and that of the starch-containing saccharide (the maize starch/lactose granulated mixture) may preferably be about 25-60 parts by weight.

If the crystalline cellulose/light anhydrous silicic acid is as little as 9.6 parts by weight, and the starch-containing saccharide is as much as 87 parts by weight (Comparative Example 7), the disintegrating property becomes significantly deteriorated, and thus undesirable. On the other hand, if the crystalline cellulose/light anhydrous silicic acid is as much as 87 parts by weight, and the starch-containing saccharide is as little as 9.6 parts by weight (Comparative Example 9), the storage stability becomes significantly deteriorated, and thus undesirable.

INDUSTRIAL APPLICABILITY

The oral fast-disintegrating tablet of the present invention, while maintaining an appropriate hardness, exhibits an excellent disintegrating property in the oral cavity, and has an excellent tablet making stability and the storage stability of the useful bacterium. Thus, it can provide a tablet that can be taken without water even by those having reduced deglutition ability such as elderly people and small children or even normal adults, without any limitation on the site of drug taking, and to patients who desire to improve disturbances in balance of the intestinal bacterial flora or the balance of the intestinal bacterial flora.

What is claimed is:

1. An oral fast-disintegrating tablet which has a useful bacterium, crystalline cellulose/light anhydrous silicic acid and a starch-containing saccharide, and a moisture content of 3.2% by weight or less.

2. The oral fast-disintegrating tablet according to claim 1 in which the useful bacterium is a Bifidobacterium or a lactic acid bacterium.

3. The oral fast-disintegrating tablet according to claim 1 in which the useful bacterium is a Bifidobacterium .

4. The oral fast-disintegrating tablet according to any one of claims 1 to 3 comprising 35-70 parts by weight of crystalline cellulose/light anhydrous silicic acid relative to 100 parts by weight of the tablet.

5. The oral fast-disintegrating tablet according to any one of claims 1 to 3 comprising 25-60 parts by weight of a starch-containing saccharide relative to 100 parts by weight of the tablet.

6. The oral fast-disintegrating tablet according to any one of claims 1 to 3 comprising 40-70 parts by weight of crystalline cellulose/light anhydrous silicic acid and 30-60 parts by weight of a starch-containing saccharide relative to 100 parts by weight of the tablet.

7. The oral fast-disintegrating tablet according to any one of claims 1 to 6 in which the tablet hardness is 30N-60N.

8. A method of producing an oral fast-disintegrating tablet said method comprising compression-molding a mixed powder of a useful bacterium, crystalline cellulose/light anhydrous silicic acid and a starch-containing saccharide in the dry form to obtain a tablet with a moisture content of 3.2% by weight or less.