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CA 2492490 C 2014/07/08

(11)(21) **2 492 490**

(12) **BREVET CANADIEN**  
**CANADIAN PATENT**

(13) **C**

(86) Date de dépôt PCT/PCT Filing Date: 2003/07/28  
(87) Date publication PCT/PCT Publication Date: 2004/02/05  
(45) Date de délivrance/Issue Date: 2014/07/08  
(85) Entrée phase nationale/National Entry: 2005/01/12  
(86) N° demande PCT/PCT Application No.: JP 2003/009529  
(87) N° publication PCT/PCT Publication No.: 2004/010969  
(30) Priorité/Priority: 2002/07/29 (JP2002-220191)

(51) Cl.Int./Int.Cl. *A61K 9/00* (2006.01),  
*A61K 47/36* (2006.01)

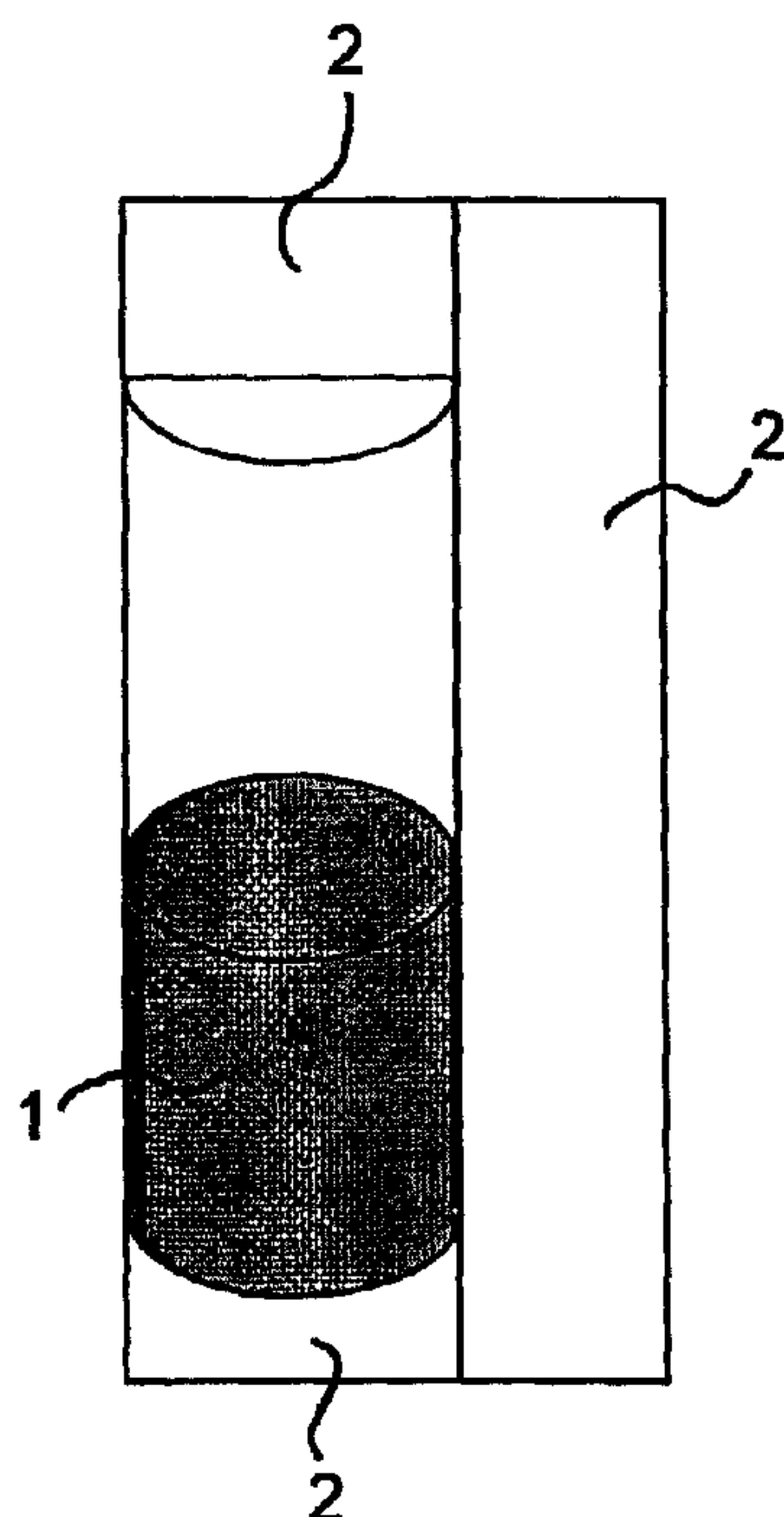
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(54) Titre : COMPOSITION D'HERBORISTERIE CHINOISE SOUS FORME DE GELEE

(54) Title: CHINESE HERBAL MEDICAL COMPOSITION IN THE FORM OF JELLY



(57) Abrégé/Abstract:

The present invention is directed to a Chinese herbal medical composition in the form of jelly, wherein a Chinese herbal medicine is contained in a base containing at least one substance selected from the group consisting of carrageenan, carob bean gum and xanthan gum and not containing phosphate buffer, which hardly causes syneresis, has superior preservative stability, especially is broadly applicable to a Chinese herbal medicine and is orally taken without taking care of the bitter taste of a Chinese herbal medicine.

## ABSTRACT

The present invention is directed to a Chinese  
herbal medical composition in the form of jelly,  
wherein a Chinese herbal medicine is contained in a base containing at  
5 least one substance selected from the group consisting of carrageenan,  
carob bean gum and xanthan gum and not containing phosphate buffer,  
which hardly causes syneresis, has superior preservative stability,  
especially is broadly applicable to a Chinese herbal medicine and is  
orally taken without taking care of the bitter taste of a Chinese herbal  
10 medicine.

## CHINESE HERBAL MEDICAL COMPOSITION IN THE FORM OF JELLY

## 5 TECHNICAL FIELD

The present invention relates to a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, has superior preservative stability, especially is broadly applicable to Chinese herbal medicine and can be orally taken without taking care of the bitter taste, etc., of the Chinese herbal medicine.

## BACKGROUND ART

Traditional Chinese herbal medicines are in the forms of liquids prepared by decocting crude drugs, powders prepared by 15 powdering crude drugs or pills made of crude drugs and honey and therefore, have many inconvenient features due to the time it takes to decoct crude drugs and due to having to prepare it as needed. Furthermore, when a patient takes the decoction or the powdered crude drug, it is painful or difficult to 20 take due to the bitter taste or smell peculiar to Chinese herbal medicines. There were such problems peculiar to Chinese herbal medicines.

Nowadays, in order to solve such problems, Chinese herbal medical preparations, such as extracts from a Chinese herbal medicine, 25 powders, granules, tablets, liquids, etc., prepared starting from the powdered crude drugs are used. These preparations solve the inconveniences due to the time it takes to decoct crude drugs and due to having to prepare it as needed. They are also superior

in preservative stability.

However, a patient must take several grams in the form of powders, granules or tablets, and it is a burden for the patient to take them in such quantities. In addition, in regard to the powders and the granules, there are such problems as choking, a sandy feeling in a mouth, or getting between false teeth when they are taken. In regard to the tablets, they are too large to swallow. The taste and smell peculiar to Chinese herbal medicines is improved by tabletting it, but some problems remain such that Chinese herbal medicines have strong tastes and can be 5 unpleasant and difficult to take it when the contents in the tablets dissolve or the tablets disintegrate in the mouth while taking them.

On the other hand, in regard to the liquids they are more easily taken compared with the powders, the granules and the tablets, but there are such troubles that the bitter taste and smell peculiar to 10 Chinese herbal medicines becomes strong because the liquid is broadly spread in the mouth and therefore, it is painful and difficult to take. Furthermore, it is inconvenient for carrying as it is packed in a glass-bottle. In order to solve such problems with Chinese herbal medical preparations, it has been considered to make a Chinese herbal medicine 15 in the form of jelly.

As a jelly preparation containing a Chinese herbal medicine, there is known a jelly preparation made of a Chinese herbal medicine and gelatin (Japanese patent publication B 7-116049). As gelatin is a 20 gelling agent which is physico-chemically unstable, the preparation lacks in the preservative stability and must be stored in a cold place. Therefore, it does not stand for the test for medicines (the long term-preservation test at 25°C under 60 % RH for 3 years, or the accelerated 25 preservation test at 40°C under 75 % RH for 6 months, etc.). In

addition, gelatin is easily dissolved in the mouth and therefore, the preparation easily gives the bitter taste and is not easy to take when the Chinese herbal medicine having the strong bitter taste is contained therein.

In addition, it is usual that a jelly preparation containing a Chinese herbal medicine is prepared using sodium alginate or agar. As a jelly preparation containing a Chinese herbal medicine by using sodium alginate, there is known a jelly preparation containing Shosaiko-to (Japanese patent No.2508547). The bitter taste peculiar to a Chinese herbal medicine can be masked by adding alginic acid. However, as jelly containing alginic acid causes much syneresis, heterogeneity of the drug occurs and the drug in the packed vessel remains when taking it. The appearance is also bad. Therefore, the preparation is not preferable as a medicine.

In regard to a jelly preparation prepared by using agar, the preparation causes much syneresis, as well as the preparation containing alginic acid and further, the preparation easily disintegrates in the mouth, easily gives the bitter taste and does not give a good feeling when taking it.

As other jelly preparations, a jelly composition (Japanese patent publication A 9-187233 and Japanese patent publication A 9-194346) and a Chinese herbal medical composition in the form of jelly (Japanese patent publication A 2001-114696) are known, but it is very difficult especially to prepare jelly preparations containing a Chinese herbal medicine which guarantees the preservative stability to a medical level.

As causes for these difficulties to make a Chinese herbal medicine in the form of jelly, the following reasons are considered.

The preparation contains as a starting material, a natural product which consists of a variety of ingredients, and many of these ingredients

are structurally unknown. In addition, in the forms as the starting material, there are many kinds such as crude drugs, liquid extract, condensed extract, dry extract, soft extract, fluid extract, etc., and the dosages vary.

5 As there is such a background peculiar to Chinese herbal medicines, when a Chinese herbal medicine is formed into a jelly preparation, according to the type of contained Chinese herbal medicine or its amount, there are possibilities to produce the preparation wherein its appearance cannot be maintained due to  
10 syneresis and the stability of the active ingredients cannot be maintained. Therefore, a Chinese herbal medical composition in the form of jelly which is broadly applicable is desired.

#### DISCLOSURE OF INVENTION

15 The present invention was completed based on the above viewpoint and its problem is to provide a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in preservative stability, especially is broadly applicable to a Chinese herbal medicine and is orally taken without the need to take care of the  
20 bitter taste, etc., of a Chinese herbal medicine.

The present inventors have extensively studied to solve the above problems, and it has been found that by using at least one substance selected from the group consisting of carrageenan, carob bean gum and xanthan gum as a base (not containing phosphate buffer) of the jelly preparation containing a Chinese herbal medicine, a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in preservative stability, especially is broadly applicable to a Chinese herbal medicine and is orally taken

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without the need to take care of the bitter taste, etc., of a Chinese herbal medicine is obtainable. Thus the present invention was completed.

In one particular embodiment there is provided a Chinese herbal  
5 medical composition in the form of jelly wherein a Chinese herbal  
medicine is contained in an amount of less than 60 w/w % per total  
amount in a base containing a combination of 0.01 to 10.0 w/w % per  
total amount of carrageenan, 0.01 to 10.0 w/w % per total amount of  
carob bean gum and 0.05 to 5.0 w/w % per total amount of xanthan  
10 gum and not containing phosphate buffer, and the carrageenan is  
1 carrageenan.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a stick-like packed vessel which is sealed on three parts.

## Explanation of signs

5

- 1: A Chinese herbal medical composition in the form of jelly
- 2: Sealed parts

## PREFERABLE MODE FOR CARRYING OUT THE INVENTION

10

Carrageenan used in a Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is usually used for a jelly composition. For example, there are  $\kappa$  (kappa) type,  $\iota$  (iota) type and  $\lambda$  (lambda) type in respect to carrageenan. Any type is suitable, but preferably a combination of  $\iota$  type carrageenan and either  $\kappa$  type carrageenan or  $\lambda$  type carrageenan, or a combination of these three types of carageenan, or  $\iota$  type carrageenan solely is suitable.

15

When a combination of  $\iota$  type carrageenan and either  $\kappa$  type carrageenan or  $\lambda$  type carrageenan, or a combination of these three types of carageenan is used,  $\iota$  type carrageenan is usually used in the amount of more than 50 w/w % per total carageenan weight, preferably more than 70 w/w %, and more preferably more than 95 w/w %.

20

The amount of carageenan contained in a Chinese herbal medical composition in the form of jelly of the present invention is preferably 0.01~10.0 w/w % per total amount of the composition, more preferable 0.05~5.0 w/w %, and further more preferably 0.08~2.0 w/w %. When the amount of carrageenan is beyond the above range, the preparation

25

becomes too viscous to prepare it and when the amount is below the above range, the jelly formation becomes difficult and the desired composition cannot be obtained.

5 Carob bean gum used in a Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is usually used for a jelly composition.

10 The amount of carob bean gum contained in a Chinese herbal medical composition in the form of jelly of the present invention is preferably 0.01~10.0 w/w % per total amount of the composition, more preferable 0.05~5.0 w/w %, and further more preferably 0.1~2.0 w/w %. When the amount of carob bean gum is beyond the above range, the preparation becomes too viscous to prepare it and when the amount is below the above range, the jelly formation becomes difficult and the desired composition cannot be obtained.

15 Xanthan gum used in a Chinese herbal medical composition in the form of jelly of the present invention is not limited as long as it is usually used for a jelly composition.

20 The amount of xanthan gum contained in a Chinese herbal medical composition in the form of jelly of the present invention is preferably 0.01~10.0 w/w % per total amount of the composition, more preferable 0.05~5.0 w/w %, and further more preferably 0.08~2.0 w/w %. When the amount of xanthan gum is beyond the above range, the preparation becomes too viscous to prepare it and when the amount is below the above range, the jelly formation becomes difficult and the desired composition cannot be obtained.

25 The amount of a Chinese herbal medicine contained in a Chinese herbal medical composition in the form of jelly of the present invention is preferably less than 60 w/w % per total amount of the composition,

more preferable less than 50 w/w %, and further more preferably less than 30 w/w %. When the amount of the Chinese herbal medicine is beyond the above range, there is a possibility that the preparation becomes too viscous to prepare it and the jelly formation becomes 5 difficult due to it being rice cake or jam-like.

A dispersion medium in order to disperse a base which is used for a Chinese herbal medical composition in the form of jelly of the present invention includes a liquid which is usually used as a dispersion medium of a jelly composition, for example water or a mixture of water 10 and a polyalcohol. Examples of the polyalcohol are glycerin, propylene glycol, etc. The amount of the dispersion medium of a Chinese herbal medical composition in the form of jelly of the present invention is, preferably 30~90 w/w % per total composition, more preferably 30~85 w/w %, and further more preferably 40~80 w/w %.

15 The Chinese herbal medical composition in the form of jelly of the present invention may, if necessary, contain various known ingredients which are acceptable as medical additives and are orally administrable, such as stabilizing agents, correctives, sweetening agents, emulsifying agents, dispersion agents, preservatives, flavors, coloring agents, etc.

20 The stabilizing agent, if desired, contained in the Chinese herbal medical composition in the form of jelly of the present invention includes ascorbic acid, disodium edetate, tocopherol, etc. The corrective includes citric acid, malic acid, lactic acid, succinic acid, tartaric acid, ascorbic acid, a citrate, a malate, a lactate, a succinate, a 25 tartarate, etc. The sweetening agent includes glucose, fructose, saccharin sodium, sucrose, D-sorbitol, D-mannitol, hydrogenated maltose starch syrup, etc. The emulsifying agent includes polyoxyethylene sorbitan monooleate, sodium lauryl sulfate, etc. The

dispersion agent includes an aqueous high molecular weight compound, such as carboxymethylcellulose, sodium alginate, hydroxypropylcellulose, hydroxyethylcellulose, etc. The preservative includes methyl parahydroxybenzoate (methylparaben), ethyl 5 parahydroxybenzoate (ethylparaben), etc. The flavor includes those such as menthols, fruit juices, or essential oils. The coloring agent includes caramel, etc.

The raw material contained in the Chinese herbal medical composition in the form of jelly of the present invention is not limited as 10 long as it is a customary Chinese herbal medicine. For example, Kakkon-to, Sho-seiryu-to, Sho-saiko-to, Hachimi-jio-gan, Hochu-ekki-to, Sho-kenchu-to, Shofu-san, Seijo-bofu-to, Bofu-tsusho-san, Gorei-san, Boi-ogi-to, Otsuji-to, 15 Toki-shakuyaku-san, Keishi-bukuryo-gan, Anchu-san, Heii-san, etc., are illustrated. Further a variety of Chinese herbal medicines are suitable as well. The raw material is not only limited in Chinese herbal medicines, but also the 20 raw material made of natural plants is usable in the Chinese herbal medical composition in the form of jelly of the present invention. The raw material selected from Chinese herbal medicines and natural plants is usable in combination with other active substances in the Chinese 25 herbal medical composition in the form of jelly of the present invention. For example, a combination of a cold medicine, an antitussive, an expectorant, a medicine for stomach with a western medicine is usable.

The raw material is not limited as long as it is a usual Chinese herbal medicine or natural plant. For example, a crude drug, liquid extract, condensed extract, dry extract, soft extract, fluid extract, etc.,

are illustrated. The amount of the raw material may be contained in order that a suitable dosage is obtained when a Chinese herbal medical composition in the form of jelly is taken in the defined amount.

The method for preparing the Chinese herbal medical composition in the form of jelly of the present invention can be the same manner as is usually known for jelly preparations. For example, a suitable amount of warmed water as a dispersion medium is added to a base and a raw material and if necessary, a desired substance, and the mixture is stirred to be dispersed, dissolved or suspended, or otherwise a suitable amount of water or cold water as a dispersion medium is added to a base and a raw material and if necessary, a desired substance at room temperature. The mixture is stirred under warming to be dispersed, dissolved or suspended and the resulting drug is cooled to prepare the Chinese herbal medical composition in the form of jelly.

Further, when an ingredient which is not preferable to be exposed to high temperature is contained among a base and a raw material and if necessary, a desired substance, it may be added after the dispersion, the solution or the suspension prepared above is adjusted to moderate temperature to prepare the Chinese herbal medical composition in the form of jelly, or otherwise an ingredient which it is not preferable to be exposed to high temperature may be added thereto just before cooling to prepare the Chinese herbal medical composition in the form of jelly.

The packed vessel for the Chinese herbal medical composition in the form of jelly of the present invention is not specifically limited, but a stick-like vessel or a bag-like vessel is preferable from the viewpoint of carrying and taking it.

#### Example

The present invention is explained by the following examples and is not limited by these examples.

Examples 1~4 and Comparative examples 1~6

In regard to Examples 1~4 and Comparative examples 1, 5 and 6, 5 the ingredients shown in Tables 1-1 and 1-2 were weighed and each ingredient was dissolved under heating at 80°C. The resulting solution was poured into a stick-like vessel sealed at three parts and cooled to prepare a Chinese herbal medical composition.

In regard to Comparative examples 2~4, after sodium 10 alginate was first homogenously dissolved in water, it was warmed at 50~60°C, and thereto were added aqueous dry extract of Kakkon-to.

After the mixture was homogenously dissolved for about 5 minutes, other residual ingredients were added thereto and stirred homogenously. The mixture was poured into a stick-like vessel sealed 15 at three parts and was cooled to prepare a Chinese herbal medical composition.

The preparation of Example 1 gave a good Chinese herbal medical composition in the form of jelly, but the preparation of Comparative example 1 became like a rice cake without forming a jelly. The 20 preparations of Examples 2~4 and Comparative example 5 gave Chinese herbal medical compositions in the form of jelly, but the preparations of Comparative examples 2~4 containing sodium alginate did not form jelly. The preparation of Comparative example 6 containing gelatin gave a Chinese herbal medical composition in the form of jelly in a 25 refrigerator, but the preparation was a semi-solid at room temperature.

Examples 5~7

The ingredients shown in Table 2 were weighed and each

ingredient was dissolved under heating at 80°C. The resulting solution was poured into a stick-like vessel sealed at three parts and was cooled to prepare a Chinese herbal medical composition in the form of jelly.

5 Examples 8~10 and Comparative examples 7~9

In regard to Examples 8~10 and Comparative examples 8 and 9, the ingredients shown in Table 3 were weighed and each ingredient was dissolved under heating at 80°C. The resulting solution was poured into a stick-like vessel sealed at three parts and was cooled to prepare a 10 Chinese herbal medical composition in the form of jelly.

In regard to Comparative example 7, after sodium alginate was first homogenously dissolved in water, it was warmed at 50~60°C, and thereto were added aqueous dry extract of Seijo-bofu-to.

15 After the mixture was homogenously dissolved for about 5 minutes, other residual ingredients were added thereto and stirred homogenously. The mixture was poured into a stick-like vessel sealed at three parts and was cooled to prepare a Chinese herbal medical composition in the form of jelly.

The preparations of Examples 8~10 gave a good Chinese herbal 20 medical composition in the form of jelly. The preparations of Comparative example 7 and Comparative example 8 containing sodium alginate and agar, respectively gave a Chinese herbal medical composition in the form of jelly. The preparation of Comparative example 9 containing gelatin gave a Chinese herbal medical 25 composition in the form of jelly in a refrigerator, but the preparation was a semi-solid at room temperature. The preparation of Comparative example 9 was dissolved in the mouth and gave a bitter taste when it was taken, and did not give a good feeling (see Table 7). The preparation

did not serve as a medicine.

Measurement of the amount of syneresis and the strength of jelly

According to the method below, the Chinese herbal medical compositions in the form of jelly obtained were stored at 40°C under 75 % RH and at 25°C under 60 % RH, respectively. The amount of syneresis and the strength of jelly were measured on each sample and their appearances were observed.

10 The method for measuring the amount of syneresis

The method was carried out by standing on end of a stick-like packed vessel sealed at three parts into which a Chinese herbal medical composition in the form of jelly was poured (fig 1). The ratio of the weight of syneresis remaining in the air portion per total amount was calculated.

The method for measuring the strength on jelly

The method was carried out by taking out a Chinese herbal medical composition in the form of jelly (sample) from a stick-like packed vessel sealed at three parts (see fig 1) after it was stored at 25°C for 24 hours, and the sample was measured at 25°C using a tool below.

Measuring tool: Rheometer CR-200D (prepared by San Kagaku)

Measuring conditions: Pressed speed, 30mm/min

Pressure-sensitive axis: Cross section 5 x 40mm x height 15mm

25 (Stainless)

Results

The results obtained on syneresis of the preparations in the form

of jelly of Examples 2~4 and Comparative example 5 were shown in Table 4-1. The preparations of Examples 2~4 were stored both at 40°C under 75 % RH and at 25°C under 60 % RH, and they hardly showed syneresis and their appearances were good. On the other hand, the 5 preparation of Comparative example 5 containing agar showed much syneresis both at 40°C under 75 % RH and at 25°C under 60 % RH. Its appearance was bad and did not serve as a medicine.

The results obtained on the jelly strength on the preparations in the form of jelly of Examples 2~4 and the preparation of Comparative 10 example 5 were shown in Table 4-2. Changes on the jelly strength on the preparations of Examples 2~4 were not observed under the preservation both at 40°C under 75 % RH and 25°C under 60 % RH. On the contrary, rapid increase of the jelly strength was observed on the preparation Comparative example 5 containing agar under the 15 preservation both at 40°C under 75 % RH and at 25°C under 60 % RH in one month.

The preparations of Examples 5~7 gave a good Chinese herbal medical composition in the form of jelly, hardly showed syneresis under the preservation conditions both at 0°C under 75 % RH and at 25°C 20 under 60 % RH (see Table 5-1), their appearances were good and changes of the jelly strength on them were not observed (see Table 5-2).

The preparations of Examples 8~10 gave a good Chinese herbal medical composition in the form of jelly, hardly showed syneresis under the preservation conditions both at 0°C under 75 % RH and at 25°C 25 under 60 % RH (see Table 6-1). Their appearances were good and changes of the jelly strength on them were not observed (see Table 6-2).

On the contrary the preparations in the form of jelly of Comparative examples 7 and 8 showed much syneresis under the

preservation conditions both at 0°C under 75 % RH and at 25°C under 60 % RH (see Table 6-1). Their appearances were bad and the jelly strength on them was greatly changed in one month and they could not serve as a medicine (see Table 6-2).

5 As mentioned above, it was ascertained that the Chinese herbal medical composition in the form of jelly of the present invention hardly shows syneresis over a long time and is superior in the preservative stability compared with a jelly preparation containing either gelatin or sodium alginate as a base.

10 When sodium alginate is used as a base, the Chinese herbal medical composition in the form of jelly is obtained or not obtained depending on the raw material. On the contrast, according to the present invention the good Chinese herbal medical composition in the form of jelly can be obtained regardless of the raw material.

15

#### Masking effect on bitter taste

By using Chinese herbal medical compositions in the form of jelly and a semi-solid preparation containing gelatin (Comparative example 9), which had the ingredients shown in Table 3, an organoleptic test 20 was carried out. The panel tests were carried out using 10 persons (5 males and 5 females) and the evaluation were shown as follows:  
 ++ : too bitter to take one, + : bitter, ± : slightly bitter, - : scarcely bitter, -- : not bitter.

25 A preparation which was prepared by dissolving aqueous dry extract of Seijo-bofu-to 7g in water (100g) was used as a control.

As shown in Table 7, in regard to the Control and the preparations of Comparative examples 8 and 9, almost all persons

answered with "too bitter to take them" (Control and Comparative example 9: 10/10, Comparative example 8: 8/10). In contrast, in regard to the preparation of Example 10, persons who answered with "too bitter to take it" and "bitter" were 3/10 and 7/10, respectively and these preparations showed better result comparing with the preparations of Control and Comparative examples 8 and 9.

The preparation of Comparative example 7 gave the almost same result as the preparation of Example 10, and persons who answered with "too bitter to take it" and "bitter" were 1/10 and 9/10, respectively.

The preparation of Comparative example 7 like the preparation of Example 10 showed better result than the aqueous solution (control), jelly preparations containing agar and gelatin, respectively (Comparative example 8 and 9). Although it is known that the bitter taste is masked by adding sodium alginate to a bitter taste substance, it seems not to exhibit any masking effect.

In regard to the preparation of Example 9, persons who answered with "slightly bitter" were 7/10 and there was none who answered with "too bitter to take it". In regard to the preparation of Example 8, persons who answered with "slightly bitter" were 8/10 and there was none who answered with "too bitter to take it" or "bitter".

As mentioned above, it was ascertained that a Chinese herbal medical composition in the form of jelly wherein the bitter taste of a Chinese herbal medicine is effectively masked was obtained. Especially by solely using 1 carrageenan, it was confirmed that the bitter taste of a Chinese herbal medicine which was contained in a high concentration was excellently masked. Furthermore, by adding a sweetening agent to the Chinese herbal medical composition in the form of jelly prepared by the present invention, it became possible to take it almost without the need to

take care of the bitter taste of a Chinese herbal medicine.

Table 1-1

Ingredient	Amount (weight %)			
	Ex. 1	Ex. 2	Ex. 3	Ex. 4
Aqueous dry extract of Kakkon-to	30	15	15	15
$\iota$ Carrageenan	0.5	1	1	-
$\kappa$ Carrageenan	-	-	0.05	1
Carob bean gum	0.1	0.25	0.25	0.25
Xanthan gum	0.2	0.45	0.45	0.45
Sodium alginate	-	-	-	-
Calcium monohydrogen phosphate	-	-	-	-
Glucono- $\delta$ -lactone	-	-	-	-
Agar	-	-	-	-
Gelatin	-	-	-	-
Powdered hydrogenated maltose starch syrup	-	6	6	6
D-Sorbitol	-	6	6	6
Glycerin	-	6	6	6
Propylene glycol	-	1	1	1
Propyl parahydroxybenzoate	0.02	0.02	0.02	0.02
Purified water	69.18	64.28	64.23	64.28
Total	100	100	100	100

Table 1-2

Ingredient	Amount (weight %)					
	Comp. ex.1*	Comp. ex.2*	Comp. ex.3*	Comp. ex.4*	Comp. ex.5	Comp. ex.6*
Aqueous dry extract of Kakkon-to	65	5	15	15	15	15
$\iota$ Carrageenan	0.5	-	-	-	-	-
$\kappa$ Carrageenan	-	-	-	-	-	-
Carob bean gum	0.1	-	-	-	-	-
Xanthan gum	0.2	-	-	-	-	-
Sodium alginate	-	0.8	0.8	2	-	-
Calcium monohydrogen phosphate	-	0.2	0.2	0.5	-	-
Glucono- $\delta$ -lactone	-	2.2	2.2	-	-	-
Agar	-	-	-	-	3	-
Gelatin	-	-	-	-	-	7.5
Powdered hydrogenated maltose starch syrup	-	-	-	-	-	-
D-Sorbitol	-	-	-	-	-	-
Glycerin	-	-	-	-	-	-
Propylene glycol	-	-	-	-	-	-
Propyl parahydroxybenzoate	0.02	0.02	0.02	0.02	0.02	0.02
Purified water	34.18	91.78	81.78	82.48	81.98	77.48
Total	100	100	100	100	100	100

\* : not solidified

Table 2

Ingredient	Amount (weight %)		
	Ex. 5	Ex. 6	Ex. 7
Soft extract of Hachimi-jio-gan	14	-	-
Keishi-bukuryo-gan (crude drug)	-	14	14
$\iota$ Carrageenan	1	1	1
$\kappa$ Carrageenan	-	-	0.1
Carob bean gum	0.2	0.25	0.25
Xanthan gum	0.4	0.45	0.45
Powdered hydrogenated maltose starch syrup	6	6	6
D-Sorbitol	6	6	6
Glycerin	6	6	6
Propylene glycol	1	1	1
Propyl parahydroxybenzoate	0.02	0.02	0.02
Purified water	65.38	65.28	65.18
Total	100	100	100

Table 3

Ingredient	Amount (weight %)						
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8	Comp. ex. 9*	Control
Aqueous dry extract of Seijo-bofu-to	14	14	14	14	14	14	7
$\lambda$ Carrageenan	1	1	-	-	-	-	-
$\kappa$ Carrageenan	-	-	1	-	-	-	-
Carob bean gum	0.2	0.2	0.2	-	-	-	-
Xanthan gum	0.4	0.4	0.4	-	-	-	-
Sodium alginate	-	-	-	2	-	-	-
Calcium monohydrogen phosphate	-	-	-	0.5	-	-	-
Agar	-	-	-	-	3	-	-
Gelatin	-	-	-	-	-	7.5	-
Powdered hydrogenated maltose starch syrup	6	-	-	-	-	-	-
D-Sorbitol	6	-	-	-	-	-	-
Glycerin	6	-	-	-	-	-	-
Propylene glycol	1	-	-	-	-	-	-
Propyl parahydroxybenzoate	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Purified water	65.38	84.38	84.38	83.48	82.98	85.48	92.98
Total	100	100	100	100	100	100	100

\*: not solidified

Table 4-1

Amount of syneresis (weight %)	40°C 75 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
After 2 days	-	-	-	-
After one month	0.2 %	0.4 %	3.3 %	8.2 %
After 3 months	0.3 %	1.5 %	4.0 %	-
After 6 months	0.8 %	1.9 %	4.4 %	-
Amount of syneresis (weight %)	25°C 60 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
After 2 days	no	no	2.3 %	3.0 %
After one month	0.4 %	0.6 %	5.0 %	9.2 %
After 3 months	1.2 %	2.0 %	4.8 %	-
After 6 months	1.0 %	2.3 %	5.4 %	-

Table 4-2

Strength	40°C 75 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
Before starting preservation	293g	300g	90g	143g
After one month	290g	314g	88g	191g
After 3 months	302g	322g	84g	-
After 6 months	297g	323g	86g	-
Strength	25°C 60 % RH			
	Example 2	Example 3	Example 4	Comp. ex. 5
Before starting preservation	293g	300g	90g	143g
After one month	285g	304g	87g	180g
After 3 months	297g	308g	88g	-
After 6 months	293g	322g	84g	-

Table 5-1

Amount of syneresis (weight %)	40°C 75 % RH			25°C 60 % RH		
	Ex. 5	Ex. 6	Ex. 7	Ex. 5	Ex. 6	Ex. 7
After 2 days	no	no	no	no	no	no
After one month	no	no	no	0.3 %	no	no
After 3 months	0.3 %	no	no	0.7 %	no	no
After 6 months	0.5 %	no	no	1.1 %	no	no

Table 5-2

Strength	40°C 75 % RH			25°C 60 % RH		
	Ex. 5	Ex. 6	Ex. 7	Ex. 5	Ex. 6	Ex. 7
Before starting preservation	163g	158g	160g	163g	158g	167g
After one month	189g	155g	161g	169g	158g	165g
After 3 months	182g	157g	164g	181g	160g	160g
After 6 months	180g	164g	166g	178g	159g	163g

Table 6-1

Amount of syneresis (weight %)	40°C 75 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8
After 2 days	-	-	-	-	-
After one month	0.2 %	0.2 %	4.2 %	9.0 %	10.0 %
After 3 months	0.5 %	0.4 %	5.2 %	-	-
After 6 months	0.8 %	0.5 %	5.0 %	-	-
Amount of syneresis (weight %)	25°C 60 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8
After 2 days	0.2 %	0.2 %	3.3 %	0.9 %	4.0 %
After one month	1.1 %	1.2 %	4.4 %	8.4 %	9.7 %
After 3 months	1.0 %	1.3 %	5.1 %	-	-
After 6 months	1.2 %	1.4 %	5.2 %	-	-

Table 6-2

Strength	40°C 75 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8
Before starting preservation	276g	109g	103g	105g	68g
After one month	292g	122g	100g	69g	153g
After 3 months	286g	118g	111g	-	-
After 6 months	-	296g	114g	-	-
Strength	25°C 60 % RH				
	Ex. 8	Ex. 9	Ex. 10	Comp. ex. 7	Comp. ex. 8
Before starting preservation	276g	109g	103g	105g	68g
After one month	287g	111g	114g	64g	139g
After 3 months	284g	110g	116g	-	-
After 6 months	282g	118g	118g	-	-

Table 7

Olganoleptic test	Evaluation (Unit: person)				
	++	+	±	-	--
Ex. 8	0	0	2	8	0
Ex. 9	0	3	7	0	0
Ex. 10	3	7	0	0	0
Comp. ex. 7	1	9	0	0	0
Comp. ex. 8	8	2	0	0	0
Comp. ex. 9	10	0	0	0	0
Control	10	0	0	0	0

++ : too bitter to take one

+ : bitter

± : slightly bitter

- : scarcely bitter

-- : not bitter

## INDUSTRIAL APPLICABILITY

In the present invention, by using at least one substance selected from the group consisting of carrageenan, carob bean gum and xanthan gum as a base (not containing phosphate buffer) of the jelly preparation containing a Chinese herbal medicine, a Chinese herbal medical composition in the form of jelly, which hardly causes syneresis, is superior in preservative stability, especially is broadly applicable to a Chinese herbal medicine and is orally taken without the need to take care of the bitter taste, etc., of a Chinese herbal medicine is obtained. Furthermore, even when the Chinese herbal medical composition in the form of jelly of the present invention can stand for the test for medicines, for example the long term-preservation test at 25°C under 60 % RH for 3 years, and the accelerated preservation test at 40°C under 75 % RH for

6 months and is guaranteed in preservative stability.

## CLAIMS

1. A Chinese herbal medical composition in the form of jelly wherein a Chinese herbal medicine is contained in an amount of less than 60  
5 w/w % per total amount in a base containing a combination of 0.01 to 10.0 w/w % per total amount of carrageenan, 0.01 to 10.0 w/w % per total amount of carob bean gum and 0.05 to 5.0 w/w % per total amount of xanthan gum and not containing phosphate buffer, and the carrageenan is 1 carrageenan.  
10
2. The Chinese herbal medical composition in the form of jelly according to claim 1 wherein the Chinese herbal medicine is Kakkonto, Sho-seiryu-to, Sho-saiko-to, Hachimi-jio-gan, Hochu-ekki-to, Sho-kenchu-to, Shofu-san, Seijo-bofu-to, Bofu-tsusho-san, Gorei-san, Boi-  
15 ogi-to, Otsuji-to, Toki-shakuyaku-san, Keishi-bukuryo-gan, Anchu-san, or Heii-san.
3. The Chinese herbal medical composition in the form of jelly according to claim 2 wherein the Chinese herbal medicine is Kakkonto, Hachimi-jio-gan, Keishi-bukuryo-gan, or Seijo-bofu-to.  
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FIG 1

