

# PHARMACEUTICAL COMPOSITION FOR PREVENTING AND TREATING SENILE DEMENTIA AND PREPARATION METHOD THEREOF

## 5 TECHNICAL FIELD

[0001] The present disclosure relates to pharmaceutical fields, and in particular to a pharmaceutical composition for preventing and treating senile dementia and preparation method thereof.

## BACKGROUND

10 [0002] With accelerating of stepping into an aging society throughout the world, various gerontal neurodegenerative diseases, such as mild cognitive impairment, senile dementia and the like, have become major risk factors that threaten human health in later life and decrease life quality of old people, which brings about serious economic burden and heavy psychological pressure to the society and families. Senile dementia can be divided into  
15 Alzheimer's disease (AD), vascular dementia, and a mixed dementia that the aforementioned two diseases coexist. Senile dementia is a primary degenerative brain disease occurring in or at the early stage of the geratic period, and is a persistent dysfunction of higher-order nervous activities. Clinically, it is manifested as worsening of cognitive and memory functions, progressive deterioration of daily life ability, as well as  
20 various symptoms such as neuropsychiatric symptoms and behavior dysfunction. Senile dementia is a disease with relatively high incidence, and the data of the World Health Organization shows that currently there are approximately 20 million older people suffering from senile dementia throughout the world, and it would be expected that by 2020 there will be more than 30 million patients suffering from senile dementia  
25 throughout the world. Therefore, it is a research emphasis for medical workers of different countries throughout the world to develop a drug for improving cognition impairment and treating senile dementia, which gains great attention from Chinese and western medical professions.

[0003] Currently, drugs used for treating senile dementia mainly include an  
30 acetylcholinesterase (AChE) inhibitor, an anti-immune-inflammation drug, a calcium ion

antagonist, an antioxidant and the like. Such drugs approved by the Food and Drug Administration (FDA) (US) include donepezil, galanthamine, nimodipine, memantine hydrochloride and the like. These drugs can only temporarily relieve the deterioration of cognitive functions of the patients, but cannot suspend the progression of diseases.

Furthermore, some of the aforementioned drugs have adverse effects such as serious liver and kidney toxicities, and some of the aforementioned drugs are too expensive to be afforded by the patients and family members thereof. Thus, it still needs to develop a new drug with a good therapeutic effect, little toxic and side effects and an appropriate price. Recently, specialists and scholars from China and abroad turn their attention to traditional Chinese medicines and natural medicines, and attempt to conduct a research on treatment of senile dementia. The modern traditional Chinese medicine (TCM) believes that, senile dementia is a common gerontal disease characterized by deficiency in origin and excess in superficiality, wherein the deficiency in origin is mainly caused by deficiency of the kidney essence, deficiency of marrow sea, and failure of lucid yang to rise; kidney deficiency is the root cause of senile dementia, and malnutrition of internal organs is closely related to the incidence of senile dementia. Therefore senile dementia is often treated by tonifying Kidney and strengthening essence.

[0004] As recorded in Encyclopedia of Chinese herbal medicine, Poria has effects of removing dampness and promoting diuresis, and calming the heart and strengthening the spleen, which can be used to treat edema and oliguria, dizziness and palpitation due to fluid retention, deficiency of the spleen and lack of appetite, loose stool or diarrhoea, malaise, and palpitation due to fear and insomnia. *Acanthopanax Senticosi Radix et Rhizoma seu Caulis* (also known as “*Acanthopanax*”) has effects of invigorating qi and strengthening the spleen, and tonifying kidney and calming nerves, which is used to treat Yang deficiency of both spleen and kidney, debilitation and hypodynamia, loss of appetite, waist and knee pain, and insomnia and dreaminess. *Epimedium Folium* (also known as “*Epimedium*”) has effects of invigorating kidney and strengthening Yang; dispelling wind and eliminating dampness; strengthening muscles and bones, which is mainly used to treat impotence and spermatorrhea, deficient-cold-type infertility, frequent micturition and incontinence, kidney deficiency and cough with asthma, soreness and weakness of waist and knees, rheumatic arthralgia, hemiplegia, and insensitivity of the limbs. *Anemarrhenae Rhizoma* has effects of clearing away heat and purging pathogenic fire, nourishing Yin and moistening dryness, and quenching thirst and relieving restlessness, which may be

used to treat warm febrile diseases; high fever and polydipsia; cough or asthma; cough caused by dryness; constipation; osteopyrexia and fever; dysphoria and insomnia; and diabetes and stranguria with turbid discharge.

5 [0005] In various currently disclosed traditional Chinese medicine compositions used for treating senile dementia, formulations including one or two of the aforementioned Chinese medicinal materials may be occasionally seen. However, these formulations often include up to ten or dozens of medicinal materials and the formulated prescription has inexact therapeutic effect, and thus has uncontrollable drug quality.

## 10 SUMMARY

[0006] One of the technical problems to be resolved by the present disclosure is to provide a pharmaceutical composition for treating or preventing senile dementia with a definite curative effect.

15 [0007] In order to resolve the technical problem as mentioned above, the present disclosure in one aspect provides a pharmaceutical composition for treating or preventing senile dementia, the active ingredients of which are prepared from raw medicinal materials comprising 20-50 parts by weight of Epimedium (i.e. Epimedii Folium) and 15-55 parts by weight of Poria.

20 [0008] The present disclosure in another aspect provides a pharmaceutical composition for treating or preventing senile dementia, the active ingredients of which are prepared from raw medicinal materials comprising 20-50 parts by weight of Epimedium, 15-55 parts by weight of Poria and 10-55 parts by weight of Acanthopanax, preferably from traditional Chinese medicinal materials comprising 20-30 parts by weight of Epimedium, 20-45 parts by weight of Poria and 20-55 parts by weight of Acanthopanax,  
25 more preferably from traditional Chinese medicinal materials comprising 30 parts by weight of Epimedium, 30 parts by weight of Poria and 35 parts by weight of Acanthopanax.

[0009] The present disclosure in a further aspect provides a pharmaceutical composition for treating or preventing senile dementia, the active ingredients of which are  
30 prepared from raw medicinal materials comprising 20-50 parts by weight of Epimedium,

15-50 parts by weight of Poria, 15-50 parts by weight of Acanthopanax and 6-15 parts by weight of Anemarrhenae Rhizoma, preferably from traditional Chinese medicinal materials comprising 20-30 parts by weight of Epimedium, 20-30 parts by weight of Poria, 25-50 parts by weight of Acanthopanax, and 10-15 parts by weight of Anemarrhenae Rhizoma, more preferably from traditional Chinese medicinal materials comprising 30 parts by weight of Epimedium, 30 parts by weight of Poria, 25 parts by weight of Acanthopanax and 15 parts by weight of Anemarrhenae Rhizoma.

[0010] In the above traditional Chinese medicinal materials, Poria may be replaced by Poria cum Radix Pini or Polyporus; and Acanthopanax may be replaced by Acanthopanax Cortex (*Acanthopanax gracilistylus* W.W.Smith) or Acanthopanax Senticosi Folium (*Acanthopanax senticosus* (Rupr.et Maxim.) Harms).

[0011] In a still further aspect, the present disclosure provides a process for preparing said pharmaceutical compositions in which:

[0012] said Poria can be processed by the following steps of extracting said weight parts of Poria with water 2-3 times each for 1-3 hours wherein the first extraction is carried out with water that is 6-10 times the weight of Poria; and the second and third extractions each are carried out with water that is 4-8 times the weight of Poria; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; preferably said Poria is processed by the following steps of extracting said weight parts of Poria with water 3 times each for 1 hour wherein the first extraction is carried out with water that is 8 times the weight of Poria; and the second and third extractions each are carried out with water that is 6 times the weight of Poria; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure;

[0013] said Epimedium can be processed by the following steps of extracting said weight parts of Epimedium with 30-70% ethanol solution 2-3 times each for 1-3 hours, wherein the first extraction is carried out with 30-70% ethanol solution that is 7-16 times the weight of Epimedium; and the second and third extractions each are carried out with 30-70% ethanol solution that is 4-12 times the weight of Epimedium; filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract; preferably said Epimedium is processed by the following steps of extracting said weight parts of Epimedium with 50% ethanol solution 3

times each for 1 hour, wherein the first extraction is carried out with 50% ethanol solution that is 9 times the weight of Epimedium; the second extraction is carried out with 50% ethanol solution that is 7 times the weight of Epimedium and the third extraction is carried out with 50% ethanol solution that is 5 times the weight of Epimedium; filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract;

[0014] said Acanthopanax can be processed by the following steps of extracting said weight parts of Acanthopanax with water 2-3 times each for 1-3 hours wherein the first extraction is carried out with water that is 6-10 times the weight of Acanthopanax; and the second and third extractions each are carried out with water that is 4-8 times the weight of Acanthopanax; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; preferably said Acanthopanax is processed by the following steps of extracting said weight parts of Acanthopanax with water 3 times each for 1 hour wherein the first extraction is carried out with water that is 8 times the weight of Acanthopanax; and the second and third extractions each are carried out with water that is 6 times the weight of Acanthopanax; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; and

[0015] said Anemarrhenae Rhizoma can be processed by the following steps of placing said weight parts of Anemarrhenae Rhizoma into water that is 6-10 times the weight of Anemarrhenae Rhizoma, heating the water until it boils and then decocting Anemarrhenae Rhizoma for 2-4 hours, removing and keeping the supernatant liquid, repeating the above process on the resulting residue again, and then filtering the combined extract solution followed by concentrating it into a dry extract; preferably said Anemarrhenae Rhizoma is processed by the following steps of placing said weight parts of Anemarrhenae Rhizoma into water that is 6 times the weight of Anemarrhenae Rhizoma, heating the water until it boils and then decocting Anemarrhenae Rhizoma for 2 hours, removing and keeping the supernatant liquid, repeating the extraction process on the resulting residue again, and then filtering the combined extract solution followed by concentrating it into a dry extract.

[0016] In one embodiment of the present disclosure, the pharmaceutical composition comprising Epimedium and Poria is formed by uniformly mixing the above dried

Epimedium extract and above dried Poria extract. In one embodiment of the present disclosure, the pharmaceutical composition comprising Epimedium, Poria and Acanthopanax is formed by uniformly mixing the above dried Epimedium extract, above dried Poria extract and above dried Acanthopanax extract. In one embodiment of the present disclosure, the pharmaceutical composition comprising Epimedium, Poria, Acanthopanax and Anemarrhenae Rhizoma is formed by uniformly mixing the above dried Epimedium extract, above dried Poria extract, above dried Acanthopanax extract and above dried Anemarrhenae Rhizoma extract.

[0017] Moreover, the present disclosure provides a process for preparing said pharmaceutical compositions comprising Epimedium, Poria and Acanthopanax, which process comprises the following steps:

[0018] extracting said weight parts of Poria and said weight parts of Acanthopanax, separately or in combination, with water 2-3 times each for 1-3 hours, wherein the first extraction is carried out with water that is 6-10 times by weight; and the second and third extractions each are carried out with water that is 4-8 times by weight; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; preferably extracting a mixture of said weight parts of Poria and said weight parts of Acanthopanax with water 3 times, each for 1 hour wherein the first extraction is carried out with water that is 8 times the weight of the mixture; and the second and third extractions each are carried out with water that is 6 times the weight of the mixture; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure;

[0019] extracting said weight parts of Epimedium with 30-70% ethanol solution 2-3 times each for 1-3 hours wherein the first extraction is carried out with 30-70% ethanol solution that is 7-16 times the weight of Epimedium; and the second and third extractions each are carried out with 30-70% ethanol solution that is 4-12 times the weight of Epimedium; filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract; preferably extracting said weight parts of Epimedium with 50% ethanol solution 3 times each for 1 hour wherein the first extraction is carried out with 50% ethanol solution that is 9 times the weight of Epimedium; the second extraction is carried out with 50% ethanol solution that is 7 times

the weight of Epimedium and the third extraction is carried out with 50% ethanol solution that is 5 times the weight of Epimedium; filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract; and

5 [0020] uniformly mixing above two resulting extracts .

[0021] Furthermore, the present disclosure provides a process for preparing said pharmaceutical compositions comprising Epimedium, Poria, Acanthopanax and Anemarrhenae Rhizoma, which process comprises the following steps:

[0022] extracting said weight parts of Poria and said weight parts of Acanthopanax,  
10 separately or in combination, with water 2-3 times each for 1-3 hours, wherein the first extraction is carried out with water that is 6-10 times by weight, and the second and third extractions each are carried out with water that is 4-8 times by weight; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; preferably extracting a mixture of said weight parts of Poria and said weight parts of  
15 Acanthopanax with water 3 times, each for 1 hour wherein the first extraction is carried out with water that is 8 times the weight of the mixture; and the second and third extractions each are carried out with water that is 6 times the weight of the mixture; filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure;

20 [0023] extracting said weight parts of Epimedium with 30-70% ethanol solution 2-3 times each for 1-3 hours wherein the first extraction is carried out with 30-70% ethanol solution that is 7-16 times the weight of Epimedium; and the second and third extractions each are carried out with 30-70% ethanol solution that is 4-12 times the weight of Epimedium; filtering the resulting extract solution and recovering ethanol under reduced  
25 pressure followed by concentrating it into a dry extract; preferably extracting said weight parts of Epimedium with 50% ethanol solution 3 times each for 1 hour wherein the first extraction is carried out with 50% ethanol solution that is 9 times the weight of Epimedium; the second extraction is carried out with 50% ethanol solution that is 7 times the weight of Epimedium and the third extraction is carried out with 50% ethanol solution  
30 that is 5 times the weight of Epimedium; filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract;

[0024] placing said weight parts of Anemarrhenae Rhizoma into water that is 6-10 times the weight of Anemarrhenae Rhizoma, heating the water until it boils and then decocting Anemarrhenae Rhizoma for 2-4 hours, removing and keeping the supernatant liquid, repeating the extraction process on the resulting residue again, and then filtering the combined extract solution followed by concentrating it into a dry extract; preferably placing said weight parts of Anemarrhenae Rhizoma into water that is 6 times the weight of Anemarrhenae Rhizoma, heating the water until it boils and then decocting Anemarrhenae Rhizoma for 2 hours, removing and keeping the supernatant liquid, repeating the extraction process on the resulting residue again, and then filtering the combined extract solution followed by concentrating it into a dry extract; and

[0025] uniformly mixing above three resulting extracts .

[0026] As compared with the prior art, the present disclosure provides a pharmaceutical composition with a simple formulation and definite curative effects.

## 15 DETAILED DESCRIPTION

### **Example 1. Preparation of pharmaceutical composition**

[0027] A. Extract from Epimedium (Pharmaceutical Composition A)

[0028] 3 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure.

[0029] B. Extract from Poria (Pharmaceutical Composition B)

25 [0030] 3 Kg of Poria was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of Poria, the second and third extractions each were carried out with water that was 6 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure.

[0031] C. Extract from Acanthopanax (Pharmaceutical Composition C)

[0032] 3 Kg of Acanthopanax was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of Acanthopanax, the second and third extractions each were carried out with water that was 6 times the weight of Acanthopanax. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure, yielding 0.12 kg.

[0033] D. Extract from Anemarrhenae Rhizoma (Pharmaceutical Composition D)

[0034] 3 Kg of Anemarrhenae Rhizoma was added to water that was 6 times the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that, the supernatant liquid was removed and kept, and the above process was repeated on the resulting residue again. The resulting extract solutions were combined and filtered and then concentrated into a dry extract under reduced pressure.

[0035] Preparation of Pharmaceutical Composition E consisting of 20 parts by weight of Epimedium and 50 parts by weight of Poria

[0036] 5 Kg of Poria was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of Poria, the second and third extractions each were carried out with water that was 6 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 2 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. The above two resulting extracts were mixed uniformly.

[0037] Preparation of Pharmaceutical Composition F consisting of 40 parts by weight of Epimedium and 55 parts by weight of Poria

[0038] 1.1 Kg of Poria was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of Poria, the second and

third extractions each were carried out with water that was 6 times the weight of Poria, respectively. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 0.8 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. The above two resulting extracts were mixed uniformly.

10 **[0039]** Preparation of Pharmaceutical Composition F' consisting of 40 parts by weight of Epimedium and 55 parts by weight of Poria

**[0040]** 1.1 Kg of Poria was extracted with water 2 times each for 3 hour. The first extraction was carried out with water that was 6 times the weight of Poria, the second extraction was carried out with water that was 4 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 1 Kg of Epimedium was extracted with 70% ethanol solution 2 times each for 1 hour. The first extraction was carried out with 70% ethanol solution that was 7 times the weight of Epimedium and the second extraction was carried out with 70% ethanol solution that was 4 times the weight of Epimedium. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. The above two resulting extracts were mixed uniformly.

**[0041]** Preparation of Pharmaceutical Composition G consisting of 50 parts by weight of Epimedium and 15 parts by weight of Poria

25 **[0042]** 0.3 Kg of Poria was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of Poria, and the second and third extractions each were carried out with water that was 6 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 1 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried

out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered and ethanol was recovered under reduced pressure followed by concentrating it into a dry extract. The above two resulting extracts were mixed uniformly.

- 5    **[0043]**    Preparation of Pharmaceutical Composition **G'** consisting of 50 parts by weight of Epimedium and 15 parts by weight of Poria

10    **[0044]**    0.3 Kg of Poria was extracted with water 2 times each for 3 hours. The first extraction was carried out with water that was 10 times the weight of Poria and the second extractions was carried out with water that was 8 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 1 Kg of Epimedium was extracted with 30% ethanol solution 2 times each for 3 hours. The first extraction was carried out with 30% ethanol solution that was 16 times the weight of Epimedium and the second extraction was carried out with 30% ethanol solution that was 12 times the weight of Epimedium. The resulting extract solution was filtered and  
15 then concentrated into a dry extract under reduced pressure after recovering ethanol. The above two resulting extracts were mixed uniformly.

**[0045]**    Preparation of Pharmaceutical Composition **H** consisting of 50 parts by weight of Epimedium, 15 parts by weight of Poria and 10 parts by weight of Acanthopanax

20    **[0046]**    1 Kg of Acanthopanax was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of Acanthopanax and the second and third extractions each were carried out with water that was 6 times the weight of Acanthopanax. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 1.5 Kg of Poria was extracted with water 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight  
25 of Poria and the second and third extractions each were carried out with water that was 6 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 5 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was  
30 carried out with 50% ethanol solution that was 7 times the weight of Epimedium and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of

Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting three extracts were mixed uniformly.

5 [0047] Preparation of Pharmaceutical Composition H' consisting of 50 parts by weight of Epimedium, 15 parts by weight of Poria and 10 parts by weight of Acanthopanax

10 [0048] 1 Kg of Acanthopanax was extracted with water 2 times each for 1 hour. The first extraction was carried out with water that was 6 times the weight of Acanthopanax and the second and third extractions each were carried out with water that was 4 times the weight of Acanthopanax. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 1.5 Kg of Poria was extracted with water 2 times each for 3 hours. The first extraction was carried out with water that was 6 times the weight of Poria and the second extraction was carried out with water that was 4 times the weight of Poria. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 5 Kg of Epimedium was extracted with 70% ethanol solution 2 times each for 1 hour. The first extraction was carried out with 70% ethanol solution that was 7 times the weight of Epimedium and the second extraction was carried out with 70% ethanol solution that was 4 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting three extracts were mixed uniformly.

[0049] Preparation of Pharmaceutical Composition I consisting of 25 parts by weight of Epimedium, 45 parts by weight of Poria and 25 parts by weight of Acanthopanax

25 [0050] A mixture of 9 kg of Poria and 5 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 5 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of

30

Epimedium and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting two extracts were mixed uniformly.

- 5    **[0051]**    Preparation of Pharmaceutical Composition **J** consisting of 30 parts by weight of Epimedium, 30 parts by weight of Poria and 35 parts by weight of Acanthopanax

10    **[0052]**    A mixture of 3 kg of Poria and 3.5 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 3 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of  
15    Epimedium and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting two extracts were mixed uniformly.

- 20    **[0053]**    Preparation of Pharmaceutical Composition **K** consisting of 20 parts by weight of Epimedium, 40 parts by weight of Poria and 55 parts by weight of Acanthopanax

25    **[0054]**    A mixture of 0.8 kg of Poria and 1.1 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 0.4 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium and the third extraction was carried out with 50% ethanol solution that was 5  
30    times the weight of Epimedium. The resulting extract solution was filtered, ethanol was

recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting two extracts were mixed uniformly.

**[0055]** Preparation of Pharmaceutical Composition L consisting of 20 parts by weight of Epimedium, 55 parts by weight of Poria and 20 parts by weight of Acanthopanax

5 **[0056]** A mixture of 1.1 kg of Poria and 0.4 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 0.4 Kg of Epimedium was  
10 extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was  
15 recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting two extracts were mixed uniformly.

**[0057]** Preparation of Pharmaceutical Composition L' consisting of 20 parts by weight of Epimedium, 55 parts by weight of Poria and 20 parts by weight of Acanthopanax

**[0058]** A mixture of 1.1 kg of Poria and 0.4 kg of Acanthopanax was extracted 2 times  
20 each for 3 hours. The first extraction was carried out with water that was 10 times the weight of the mixture and the second extraction was carried out with water that was 8 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 0.4 kg of Epimedium was extracted with 30% ethanol solution 2 times each for 3 hours. The first extraction was carried out  
25 with 30% ethanol solution that was 16 times the weight of Epimedium, the second and third extractions each were carried out with 30% ethanol solution that was 12 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. The above resulting two extracts were mixed uniformly.

[0059] Preparation of Pharmaceutical Composition **M** consisting of 50 parts by weight of Epimedium, 15 parts by weight of Poria, 15 parts by weight of Acanthopanax and 15 parts by weight of Anemarrhenae Rhizoma

5 [0060] A mixture of 3 kg of Poria and 3 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 10 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out  
10 with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated  
15 into a dry extract. 3 Kg of Anemarrhenae Rhizoma was added to water that was 6 times the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that the supernatant liquid was removed and kept, and the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced pressure.  
20 The above resulting three extracts were mixed uniformly.

[0061] Preparation of Pharmaceutical Composition **M'** consisting of 50 parts by weight of Epimedium, 15 parts by weight of Poria, 15 parts by weight of Acanthopanax and 15 parts by weight of Anemarrhenae Rhizoma

25 [0062] A mixture of said parts by weight of Poria and said parts by weight of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 6 times the weight of the mixture and the second and third extractions each were carried out with water that was 4 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. Epimedium in above parts by weight was extracted with 30% ethanol solution 3  
30 times each for 3 hours. The first extraction was carried out with 30% ethanol solution that was 16 times the weight of Epimedium, the second and third extractions each were carried

out with 30% ethanol solution that was 12 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. Anemarrhenae Rhizoma in said parts by weight was added to water that was 6 times the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that the supernatant was taken, the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced pressure. The above resulting three extracts were mixed uniformly.

- 10    **[0063]**    Preparation of Pharmaceutical Composition N consisting of 25 parts by weight of Epimedium, 30 parts by weight of Poria, 30 parts by weight of Acanthopanax and 10 parts by weight of Anemarrhenae Rhizoma

- 15    **[0064]**    A mixture of 6 kg of Poria and 6 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 5 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second  
20    extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. 2 Kg of Anemarrhenae Rhizoma was added to water that was 6 times  
25    the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that the supernatant was removed and kept, and the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced pressure. The above resulting three extracts were mixed uniformly.

[0065] Preparation of Pharmaceutical Composition **O** consisting of 30 parts by weight of Epimedium, 30 parts by weight of Poria, 25 parts by weight of Acanthopanax and 15 parts by weight of Anemarrhenae Rhizoma

5 [0066] A mixture of 6 kg of Poria and 5 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 6 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out  
10 with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was  
15 concentrated into a dry extract. 3 Kg of Anemarrhenae Rhizoma was added to water that was 6 times the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that the supernatant was removed and kept, and the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced  
20 pressure. The above resulting three extracts were mixed uniformly.

[0067] Preparation of Pharmaceutical Composition **P** consisting of 20 parts by weight of Epimedium, 20 parts by weight of Poria, 50 parts by weight of Acanthopanax and 12 parts by weight of Anemarrhenae Rhizoma

25 [0068] A mixture of 2 kg of Poria and 5 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 2 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out  
30 with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of

Epimedium, and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. 1.2 Kg of Anemarrhenae Rhizoma was added to water that was 6 times the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that the supernatant was removed and kept, and the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced pressure. The above resulting three extracts were mixed uniformly.

- 10 [0069] Preparation of Pharmaceutical Composition Q consisting of 20 parts by weight of Epimedium, 50 parts by weight of Poria, 24 parts by weight of Acanthopanax and 6 parts by weight of Anemarrhenae Rhizoma

- 15 [0070] A mixture of 5 kg of Poria and 2.4 kg of Acanthopanax was extracted 3 times each for 1 hour. The first extraction was carried out with water that was 8 times the weight of the mixture and the second and third extractions each were carried out with water that was 6 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 2.0 Kg of Epimedium was extracted with 50% ethanol solution 3 times each for 1 hour. The first extraction was carried out with 50% ethanol solution that was 9 times the weight of Epimedium, the second extraction was carried out with 50% ethanol solution that was 7 times the weight of Epimedium, and the third extraction was carried out with 50% ethanol solution that was 5 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. 0.6 Kg of Anemarrhenae Rhizoma was added to water that was 6 times the weight of Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 2 hours. After that the supernatant was removed and kept, and the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced pressure. The above resulting three extracts were mixed uniformly.

[0071] Preparation of Pharmaceutical Composition **Q**’ consisting of 20 parts by weight of Epimedium, 50 parts by weight of Poria, 24 parts by weight of Acanthopanax and 6 parts by weight of Anemarrhenae Rhizoma

5 [0072] A mixture of 5 kg of Poria and 2.4 kg of Acanthopanax was extracted 2 times each for 3 hours. The first extraction was carried out with water that was 10 times the weight of the mixture and the second extraction was carried out with water that was 8 times the weight of the mixture. The resulting extract solution was filtered and then concentrated into a dry extract under reduced pressure. 2.0 Kg of Epimedium was extracted with 70% ethanol solution 2 times each for 1 hour. The first extraction was  
10 carried out with 70% ethanol solution that was 7 times the weight of Epimedium and the second extraction was carried out with 70% ethanol solution that was 4 times the weight of Epimedium. The resulting extract solution was filtered, ethanol was recovered from the solution under reduced pressure and then the solution was concentrated into a dry extract. 0.6 Kg of Anemarrhenae Rhizoma was added to water that was 10 times the weight of  
15 Anemarrhenae Rhizoma, the water was heated to boiling and Anemarrhenae Rhizoma was decocted for 4 hours. After that the supernatant was removed and kept, and the above process was repeated on the resulting residue again. Then the combined extract solution was filtered and concentrated into a dry extract under reduced pressure. The above resulting three extracts were mixed uniformly.

20 [0073] Preparation of Pharmaceutical Composition **R**

[0074] The preparation process was the same as that of Pharmaceutical Composition J with the exception that Poria was replaced by Poria cum Radix Pini.

[0075] Preparation of Pharmaceutical Composition **S**

25 [0076] The preparation process was the same as that of Pharmaceutical Composition J with the exception that Poria was replaced by Polyporus.

[0077] Preparation of Pharmaceutical Composition **T**

[0078] The preparation process was the same as that of Pharmaceutical Composition J with the exception that Acanthopanax was replaced by Acanthopanax Cortex.

[0079] Preparation of Pharmaceutical Composition **U**

[0080] The preparation process was the same as that of Pharmaceutical Composition J with the exception that *Acanthopanax* was replaced by *Acanthopanax Senticosi Folium*.

**Example 2: Effect on learning and memory in rats using Scopolamine-induced Model**

[0081] 1. Materials

5 Materials: Morris water maze device available from Tai Meng Technology Co. LTD, Chengdu City, China, DT-200 jump platform available from Tai Meng Technology Co. LTD, Chengdu City, China, Scopolamine Hydrobromide injection (Scop) available from Hua Yida Medical Technology Co. LTD, Wuhan City, China, and Donepezil Hydrochloride available from Eisai China Inc., China, specification: 5 mg, batch No.  
10 120829A were used.

Animals: SD Male rats, available from Da Shuo Biological Technology Co. LTD, Chengdu City, China, were used.

[0082] 2. Testing Method

[0083] Animal Grouping and Administration

15 [0084] Rats were randomly divided into Normal control group, Scop Model group, Positive control group (Donepezil, 1.17 mg/kg) and Experimental group (administered with a pharmaceutical composition of Example 1 in an amount of 11.08g raw medicinal materials per kg body weight). Before experiments, rats were fed by intragastric administration for 2 weeks. The normal control group and the model group were fed the  
20 same volume of distilled water. On day 9, rats were trained in the pool of Morris 2 times per day. On day 14, rats were subjected to do Morris water Maze and jump platform testing.

[0085] Model establishment and learning and memory test

[0086] On experiment day, rats were intragastrically administered. 30 Minutes later,  
25 they were administered with scopolamine hydrobromide (HBr) by intraperitoneal injections ( $2 \text{ mg} \cdot \text{kg}^{-1}$  for two days and then  $1 \text{ mg} \cdot \text{kg}^{-1}$  on day 3). 20 Minutes later, rats were subjected to Morris water Maze testing. The normal control group was intraperitoneally injected with the same volume of saline. Their swimming performance was tracked and recorded by a camera. The travel path, time spent and speed of movement  
30 of rats in 90s were recorded by a computer automatically, and the swimming distance and

escape latency for finding the platform were calculated. Jump platform experiment: rats were trained on day one, and subjected to testing on day 2. 20 Minutes before testing, rats were intraperitoneally injected with scopolamine HBr in  $5\text{mg}\cdot\text{kg}^{-1}$ . The first step down latency (SDL) and escape latency (the time required to escape from electric shock, EL) of rats were recorded.

### [0087] 3. Results

[0088] Effect on Morris water Maze tests of rats using Scopolamine induced Dysmnesia Model

[0089] Table 1 Effect on Morris water maze test ( $\bar{x}\pm s$ )

| Groups           | Number of animals (n) | Escape latency(s)   | Distance (cm)          |
|------------------|-----------------------|---------------------|------------------------|
| Normal control   | 10                    | 18.86 $\pm$ 6.03**  | 540.46 $\pm$ 100.24**  |
| Model control    | 10                    | 49.63 $\pm$ 9.15    | 2173.42 $\pm$ 388.11   |
| Positive control | 10                    | 37.27 $\pm$ 9.46**  | 1647.50 $\pm$ 286.35** |
| Composition A    | 10                    | 41.69 $\pm$ 9.13    | 1897.60 $\pm$ 337.12   |
| Composition B    | 10                    | 41.42 $\pm$ 10.80   | 1896.44 $\pm$ 298.22   |
| Composition C    | 10                    | 42.82 $\pm$ 10.06   | 1875.75 $\pm$ 272.57   |
| Composition D    | 10                    | 42.27 $\pm$ 8.60    | 1868.96 $\pm$ 293.34   |
| Composition E    | 10                    | 40.65 $\pm$ 8.87*   | 1794.70 $\pm$ 333.61*  |
| Composition F    | 10                    | 40.51 $\pm$ 8.62*   | 1826.32 $\pm$ 251.11*  |
| Composition G    | 10                    | 40.10 $\pm$ 8.71*   | 1792.36 $\pm$ 279.36*  |
| Composition J    | 10                    | 35.23 $\pm$ 8.20**  | 1644.08 $\pm$ 342.53** |
| Composition O    | 10                    | 34.66 $\pm$ 10.37** | 1641.50 $\pm$ 226.13** |

10 Compared with the model control group, \*P < 0.05 and \*\*P < 0.01.

[0090] The data in Table 1 clearly demonstrate that in the Morris water maze test, the performance of Scop induced dysmnesia model rats were improved by using pharmaceutical compositions A, B, C and D although not obvious (P > 0.05). Different improvements were achieved when using all other pharmaceutical compositions, in which

the use of composition J and composition O produced the most obvious improvement, and the difference was statistically significant ( $P < 0.01$ ).

[0091] Effect on rats jump platform test using Scopolamine induced Dismnesia Model

[0092] Table 2 Effect on rats in jump platform test(  $\bar{x} \pm s$ )

| Groups           | Number of animals(n) | SDL(s)         | EL(s)          |
|------------------|----------------------|----------------|----------------|
| Normal control   | 10                   | 100.60±14.26** | 59.41±11.80**  |
| Model control    | 10                   | 16.04±7.22     | 130.63±19.46   |
| Positive control | 10                   | 28.67±11.70**  | 109.17±11.17** |
| Composition A    | 10                   | 22.23±7.69     | 116.13±15.71   |
| Composition B    | 10                   | 20.85±7.00     | 115.96±13.43   |
| Composition C    | 10                   | 21.93±6.72     | 119.95±12.52   |
| Composition D    | 10                   | 22.76±7.60     | 119.81±13.66   |
| Composition E    | 10                   | 24.09±5.97*    | 113.70±13.00*  |
| Composition F    | 10                   | 24.61±7.37*    | 113.50±12.59*  |
| Composition G    | 10                   | 24.26±6.94*    | 113.52±11.72*  |
| Composition J    | 10                   | 27.71±6.04**   | 108.98±13.41** |
| Composition O    | 10                   | 27.83±5.67**   | 108.67±12.50** |

5 Compared with the model control group,\* $P < 0.05$  and \*\* $P < 0.01$ .

[0093] The data in Table 2 clearly demonstrate that in the rats jump platform test, the performance of Scop induced dysmnesia model rats were improved by using pharmaceutical compositions A, B, C and D although not obvious ( $P > 0.05$ ). Different improvements were achieved when using all other pharmaceutical compositions, in which  
 10 composition J and composition O produced the most obvious improvement, and the difference was statistically significant ( $P < 0.01$ ).

### Example 3. Effect on learning and memory of APPswe transgenic mice

[0094] 1. Materials

Material: Morris water maze device available from Tai Meng Technology Co. LTD,  
 15 Chengdu City, China, Home-made Object Recognition device; and Donepezil

Hydrochloride available from Eisai China Inc., Specification: 5 mg, batch number 120829A, were used.

Animals: APPswe transgenic mice in 5 months, available from Nanjing animal model institute, were used.

5 [0095] 2. Testing Method

[0096] Animal grouping and Administration

[0097] APPswe transgenic mice, half male and half female, were randomly divided into four groups: model control group, positive control group (donepezil, 1.67mg·kg<sup>-1</sup>), experimental group (administered with a pharmaceutical composition of Example 1 in an amount of 15.83g raw medicinal materials per kg body weight). APPswe mice with the same background and age (available from Nanjing animal model institute, without expression of human presenilin and amyloid precursor protein, and without suffering senile dementia) were used as the normal control group. Each group was given the corresponding drugs by intragastric administration and the normal control group and model control group were given distilled water of the same volume, once a day for 30 days.

[0098] Morris water Maze test

[0099] On day 25 to day 29 after administration, mice in each group were trained for water maze, 2 times per day. 1 Hour after the last administration, the location of the platform remained unchanged and the escape latency and swimming path of the mice for finding the platform were recorded by an automatic camera system, in which the maximum latency time was set as 120 s. The recording automatically stopped after 120s.

[00100] Object recognition test

[00101] In light of animal's habit of "loving the new and loathing the old", a home-made object recognition device was used for detection of animal learning and memory ability. The first day is the adaptation phase, during which mice were put in carton with good lighting and allowed to adapt to it and freely move for about 10 min. The second day is the familiar phase, during which two same toys were put in a box and mice were placed in the box for 10 min. Exploration time to each object was recorded. The third day is the recognition phase, during which another object was placed in the box to replace one toy and exploration time to each object

was recorded. The resolution index to the new toy in each group was calculated according to the following formula:

Resolution index = (the time to the new object - the time to the old object) / (the time to the new object + the time to the old object).

## 5 [00102] 3. Results

### [00103] 1) Effect on APPswe mice water Maze test

[00104] Table 3 Effect on Morris water maze test(  $\bar{x} \pm s$ )

| Groups           | Number of animals(n) | Escape latency(s) | Distance (cm)   |
|------------------|----------------------|-------------------|-----------------|
| Normal control   | 10                   | 50.50±9.42**      | 479.24±94.26**  |
| Model control    | 10                   | 86.14±14.30       | 982.81±160.96   |
| Positive control | 10                   | 68.23±12.00**     | 783.50±145.12** |
| Composition A    | 10                   | 73.07±14.43       | 840.02±152.86   |
| Composition B    | 10                   | 74.16±13.58       | 847.45±157.24   |
| Composition C    | 10                   | 74.70±10.82       | 842.36±149.22   |
| Composition D    | 10                   | 74.01±12.56       | 843.20±148.06   |
| Composition H    | 10                   | 69.54±13.39*      | 790.90±146.33*  |
| Composition I    | 10                   | 66.70±14.48**     | 759.20±162.61** |
| Composition J    | 10                   | 64.16±13.16**     | 751.08±175.17** |
| Composition K    | 10                   | 65.08±12.40**     | 755.08±146.47** |
| Composition L    | 10                   | 68.93±16.66*      | 792.65±192.96*  |
| Composition R    | 10                   | 68.50±15.32*      | 786.33±154.35*  |
| Composition S    | 10                   | 68.87±14.35*      | 795.12±142.72*  |
| Composition T    | 10                   | 68.92±13.03*      | 786.96±164.43*  |
| Composition U    | 10                   | 69.34±12.34*      | 803.46±172.33*  |
| Composition M    | 10                   | 67.58±15.21*      | 776.10±183.60*  |
| Composition N    | 10                   | 63.98±11.06**     | 744.57±157.55** |
| Composition O    | 10                   | 61.56±15.11**     | 736.28±149.50** |

|               |    |               |                 |
|---------------|----|---------------|-----------------|
| Composition P | 10 | 62.26±11.83** | 747.78±144.17** |
| Composition Q | 10 | 68.77±13.66*  | 782.94±156.02*  |

Compared with the model control group, \*P < 0.05 and \*\*P < 0.01.

5 [00105] The data in Table 3 clearly demonstrate that in the Morris water Maze test, the performance of APPswe mice were improved by using pharmaceutical compositions A, B, C and D although not obvious (P > 0.05). Different improvements were achieved when using all other pharmaceutical compositions, and compared with the model control group, the difference was statistically significant (P < 0.01~0.15).

[00106] 2) Effect on APPswe mice object recognition test

[00107] Table 4. Effect on object recognition test(  $\bar{x} \pm s$ )

| Groups           | Number of animals (n) | Resolution index |
|------------------|-----------------------|------------------|
| Normal control   | 10                    | 0.304±0.131**    |
| Model control    | 10                    | 0.105±0.044      |
| Positive control | 10                    | 0.176±0.051**    |
| Composition A    | 10                    | 0.147±0.053      |
| Composition B    | 10                    | 0.146±0.061      |
| Composition C    | 10                    | 0.152±0.058      |
| Composition D    | 10                    | 0.147±0.049      |
| Composition H    | 10                    | 0.174±0.074*     |
| Composition I    | 10                    | 0.188±0.064**    |
| Composition J    | 10                    | 0.197±0.078**    |
| Composition K    | 10                    | 0.184±0.055**    |
| Composition L    | 10                    | 0.175±0.067*     |
| Composition R    | 10                    | 0.169±0.074*     |
| Composition S    | 10                    | 0.166±0.056*     |
| Composition T    | 10                    | 0.168±0.072*     |
| Composition U    | 10                    | 0.168±0.080*     |

|               |    |               |
|---------------|----|---------------|
| Composition M | 10 | 0.175±0.075*  |
| Composition N | 10 | 0.196±0.045** |
| Composition O | 10 | 0.201±0.055** |
| Composition P | 10 | 0.197±0.062** |
| Composition Q | 10 | 0.174±0.079*  |

Compared with the model control group, \*P < 0.05 and \*\*P < 0.01.

[00108] The data in Table 4 clearly demonstrate that the exploration time of Appsw mice was improved by using pharmaceutical compositions A, B, C and D although not obvious (P > 0.05). Different improvements on exploration time of Appsw mice were achieved when using all other pharmaceutical compositions, and compared with model control group, the difference was statistically significant (P < 0.01~0.15).

#### **Example 4: Effect on learning and memory in mice using Scopolamine-induced Model**

##### **[00109] 1. Materials**

10 Materials: Morris water maze device available from Tai Meng Technology Co. LTD, Chengdu City, China, DT-200 jump platform available from Tai Meng Technology Co. LTD, Chengdu City, China, scopolamine HBr injection (Scop) available from Hua Yida Medical Technology Co. LTD, Wuhan City, China, and Donepezil Hydrochloride available from Eisai China Inc., China, specification: 5 mg, batch No. 120829A were used.

15 Animals: KM mice, available from Da Shuo Biological Technology Co. LTD, Chengdu City, China, were used.

##### **[00110] 2. Testing method**

##### **[00111] Animal Grouping and Administration**

20 [00112] Mice were randomly divided into Normal control group, Scop Model group, Positive control group (Donepezil, 1.67 mg/kg) and Experimental group (administered with a pharmaceutical composition of Example 1, in a dosage of 31.66g raw medicinal materials/ kg for composition A, B and C, and in a high dosage of 31.66g raw medicinal materials/ kg, a middle dosage of 15.83 g raw medicinal materials /kg and a low dosage of 7.92 g raw medicinal materials /kg for composition J). Before experiments, mice of

experimental group were fed by intragastric administration of a pharmaceutical composition for 2 weeks, while the normal control group and the model group were fed the same volume of distilled water. On day 9, mice were trained in the pool of Morris, 2 times per day. On day 14, mice were subjected to Morris water Maze testing.

5 [00113] Model establishment and learning and memory test

[00114] On experiment day, mice were fed by intragastric administration. 30 Minutes later, they were administered with Scop in a dosage of 3 mg·kg<sup>-1</sup> via intraperitoneal injection. 20 Minutes later, the mice were subjected to Morris water Maze testing. The normal control group was intraperitoneally injected with the same volume of saline. The swimming performance of mice were tracked and recorded by a camera. The travel path, time spent and speed of movement of mice in 300s were recorded by a computer automatically. The maximum latency was set as 300 s. The recording stopped after 300 s. The escape latency and swimming distance for looking for the platform were recorded.

[00115] 3. Results

15 [00116] Table 5. Effect on Mice in Morris water Maze test(  $\bar{x} \pm s$ )

| Groups                        | Number of animals (n) | Escape latency(s) | Swimming Distance (cm) |
|-------------------------------|-----------------------|-------------------|------------------------|
| Normal control                | 10                    | 92.09±10.74**     | 2052.09±232.41**       |
| Model control                 | 10                    | 176.54±18.74      | 3646.54±574.35         |
| Positive control              | 10                    | 141.42±25.85**    | 2738.70±534.75**       |
| Composition A                 | 10                    | 154.88±28.38      | 2920.88±601.84*        |
| Composition B                 | 10                    | 157.59±25.91      | 3104.59±396.84*        |
| Composition C                 | 10                    | 154.28±22.05*     | 3148.28±589.34         |
| Composition J (high dosage)   | 10                    | 133.55±28.98**    | 2453.55±511.18**       |
| Composition J (middle dosage) | 10                    | 136.95±28.74**    | 2576.95±527.11**       |
| Composition J                 | 10                    | 149.26±24.82*     | 2989.66±530.04*        |

---

(low dosage)

---

Compared with the model control group, \* $P < 0.05$  and \*\* $P < 0.01$ .

[00117] The data in Table 5 clearly demonstrate that in the Morris water maze test, various compositions produced different improvements on the performance of Scop induced dysmnnesia model mice, in which composition J in the high, middle and low dosage produced the most obvious improvement, and the difference was significant statistically ( $P < 0.01 \sim 0.05$ ).

### Example 5 Clinical Trial study

[00118] 1. Selection of subjects:

[00119] 1.1 Diagnostic Criteria:

10 [00120] The criteria of NINCDS-ADRDA-R were used, including core diagnostic criteria A, supportive features B and exclusion criteria as shown below.

[00121] Table 6. Core diagnostic criteria, supportive features and exclusion criteria

| Core diagnostic criteria                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A. Presence of an early and significant episodic memory impairment that includes the following features:                                                                                                                                                                                           |
| 1. Gradual and progressive change in memory function reported by patients or informants over more than 6 months                                                                                                                                                                                    |
| 2. Objective evidence of significantly impaired episodic memory on testing: this generally consists of recall deficit that does not improve significantly or does not normalise with clue or recognition testing and after effective encoding of previously control information                    |
| 3. The episodic memory impairment can be isolated or associated with other cognitive changes at the onset of AD or as AD advances                                                                                                                                                                  |
| Supportive features                                                                                                                                                                                                                                                                                |
| B. Presence of medial temporal lobe atrophy (MTA)                                                                                                                                                                                                                                                  |
| • Volume loss of hippocampi, entorhinal cortex, amygdala evidenced on MRI with qualitative ratings using visual scoring (referenced to well characterized population with age norms) or quantitative volumetry of regions of interest (referenced to well characterized population with age norms) |
| C. Abnormal cerebrospinal fluid biomarker                                                                                                                                                                                                                                                          |
| • Low amyloid $\beta_{1-42}$ concentrations, increased total tau concentrations, or increased phospho-tau concentrations, or combinations of the three                                                                                                                                             |

|                                                                                                                            |
|----------------------------------------------------------------------------------------------------------------------------|
| • Other well validated markers to be discovered in the future                                                              |
| D. Specific pattern on functional neuroimaging with PET                                                                    |
| • Reduced glucose metabolism in bilateral temporal parietal regions                                                        |
| • Other well validated ligands, including those that foreseeably will emerge such as Pittsburgh compound B or FDDNP        |
| E. Proven AD autosomal dominant mutation within the immediate family                                                       |
| <b>Exclusion criteria</b>                                                                                                  |
| History                                                                                                                    |
| • Sudden onset                                                                                                             |
| • Early occurrence of the following symptoms: gait disturbances, seizures, behavioural changes                             |
| Clinical features                                                                                                          |
| • Focal neurological features including hemiparesis, sensory loss, visual field deficits                                   |
| • Early extrapyramidal signs                                                                                               |
| Other medical disorders severe enough to account for memory and related symptoms                                           |
| • Non-AD dementia                                                                                                          |
| • Major depression                                                                                                         |
| • Cerebrovascular disease                                                                                                  |
| • Toxic and metabolic abnormalities, all of which may require specific investigations                                      |
| • MRI FLAIR or T2 signal abnormalities in the medial temporal lobe that are consistent with infectious or vascular insults |

**[00122]** 1.2. Inclusion criteria:

- (1) 60 Years of age or older, male or female.
- (2) Meeting the diagnostic criteria of AD, and also meeting the above criteria of TCM syndromes.
- 5 (3) Degree of education above the primary school.
- (4) Without stroke history.
- (5) Hachiski ischemic score (HIS) of below 4 points.
- (6) Clear and definite Brain MR (with brain atrophy and without other cranial lesions).
- (7) MMSE score: 9 ~ 24 scores for middle school or higher; and 9 ~ 20 scores for primary
- 10 school; CDR score: mild to moderate patients with 1 or 2 scores.

(8) Patients who have not taken any medicines for treating dementia for more than 1 week.

**[00123]** 1.3 Exclusion criteria:

(1) Patients who are subjected to severe cardiac or cerebral vascular diseases, severe liver or kidney disease, or pulmonary infection.

5 (2) Patients who can't cooperate with the treatment or are subjected to drug allergy.

(3) Patients who are subjected to severe depression (as demonstrated by depression table).

(4) Patients who are subjected to vascular dementia (VD), Parkinson disease dementia (PDD), dementia with Lewy bodies (DLB), frontotemporal dementia (FTD) or the like.

10 (5) Severe AD patients or patients who are subjected to severe neurological impairment so that inspection cannot be completed.

(6) Patients who are taking Aricept, Memantine, Huperzine A, Nimodipine, Ginseng, Ginkgo folium, saffron or the like currently or within 1 week.

**[00124]** 1.4 Removal or failure criteria:

15 (1) Patients who have poor medication compliance or fail to take medicine for more than 1 month.

(2) Patients who are subjected to serious diseases and have to stay in hospital.

(3) Patients who do not meet the inclusion criteria but have been mistakenly included or who meet the inclusion criteria but have failed to comply with the prescribed medication.

**[00125]** 1.5 Termination criteria:

20 (1) Patients who suffer other severe disease in the course of the trial.

(2) Patients with serious adverse events during the trial or patients whose treatments have to stop according to the doctor's judgment.

(3) Patients who cannot continue to be treated due to non-therapeutic reasons or drop out voluntarily.

25

**[00126]** 2. Preparation and administration of trial medicines

[00127] 350Kg of Acanthopanax, 300kg of Epimedium and 300kg of Poria were extracted as above, thereby affording 26 kg of extract from Acanthopanax and Poria and 54 kg of extract from Epimedium. The obtained extracts were pulverized, added with a proper amount of starch and dextrin, and then made into granules. After sterilization, the medicament was packaged in 8g/bag. The medicament was administered in a dosage of one bag twice per day, morning and evening. The daily dosage of raw medicinal materials for adults was 30 g of Epimedium, 35 g of Acanthopanax and 30g of Poria. The treatment cycle was 6 months.

### [00128] 3. Observation

10 [00129] The following observations were made on patients before enrollment and during the 6 months of treatment:

- (1) ADAS-cog scale.
- (2) MMSE scale.
- (3) Activities of daily living scale (ADL).
- 15 (4) Clinical dementia rating scale (CDR).
- (5) Neuropsychiatric Inventory scale (NPI).

### [00130] 4. Standard for evaluation of curative effect

#### [00131] Main index

- 20 (1) Cognitive function assessment: comparison of MMSE, ADAS-cog, and CDR scores with baseline levels.
- (2) Overall situation: CDR overall assessment.

#### [00132] Secondary index

- (1) Assessment of activities of daily living activities: change of ADL scores before and after treatment.
- 25 (2) Evaluation of mental behavior: comparative analysis on change of the neuropsychiatric inventory scale (NPI) scores before and after treatment.

### [00133] 5. Study results

**[00134]** Table 7 Part of the clinical data

| No. | Gender | Age | Before administration |          |     |     |     | After 6 months' administration |          |     |     |     |
|-----|--------|-----|-----------------------|----------|-----|-----|-----|--------------------------------|----------|-----|-----|-----|
|     |        |     | MMSE                  | ADAS-cog | ADL | NPI | CDR | MMSE                           | ADAS-cog | ADL | NPI | CDR |
| 1   | M      | 78  | 20                    | 29       | 28  | 1   | 1   | 21                             | 25       | 20  | 0   | 0.5 |
| 2   | F      | 80  | 12                    | 36       | 31  | 5   | 1   | 17                             | 30       | 22  | 0   | 1   |
| 3   | F      | 76  | 20                    | 38       | 39  | 3   | 1   | 19                             | 27       | 24  | 0   | 1   |
| 4   | M      | 73  | 19                    | 22       | 26  | 0   | 1   | 27                             | 13       | 20  | 0   | 0.5 |
| 5   | M      | 80  | 9                     | 45       | 27  | 6   | 2   | 11                             | 41       | 31  | 7   | 2   |
| 6   | F      | 73  | 13                    | 49       | 37  | 0   | 2   | 20                             | 41       | 33  | 0   | 2   |
| 7   | M      | 81  | 14                    | 38       | 42  | 5   | 2   | 24                             | 26       | 38  | 1   | 1   |
| 8   | M      | 74  | 21                    | 26       | 24  | 0   | 1   | 27                             | 17       | 20  | 0   | 0.5 |
| 9   | F      | 74  | 12                    | 54       | 40  | 11  | 2   | 13                             | 38       | 30  | 0   | 1   |
| 10  | F      | 76  | 15                    | 37       | 24  | 0   | 1   | 21                             | 24       | 24  | 0   | 1   |
| 11  | F      | 64  | 23                    | 24       | 24  | 0   | 1   | 28                             | 15       | 20  | 0   | 0.5 |
| 12  | F      | 79  | 19                    | 32       | 27  | 0   | 1   | 26                             | 18       | 23  | 0   | 0.5 |
| 13  | F      | 78  | 10                    | 55       | 33  | 3   | 2   | 17                             | 35       | 27  | 0   | 1   |
| 14  | M      | 77  | 13                    | 45       | 41  | 2   | 2   | 18                             | 35       | 29  | 1   | 1   |
| 15  | F      | 84  | 13                    | 43       | 36  | 2   | 2   | 17                             | 39       | 32  | 0   | 1   |
| 16  | F      | 72  | 21                    | 26       | 27  | 2   | 1   | 25                             | 15       | 20  | 0   | 0.5 |

**[00135]** The above clinical data of table 7 were statistically analyzed and the results were as follows:

5 **[00136]** Table 8-1 Effect on MMSE, ADAS-cog and CDR scores ( $\bar{x} \pm s$ , n=16)

| Group              | MMSE                  |                      | ADAS-cog              |                      | CDR                   |                      |
|--------------------|-----------------------|----------------------|-----------------------|----------------------|-----------------------|----------------------|
|                    | Before administration | After administration | Before administration | After administration | Before administration | After administration |
| Experimental group | 15.88±4.46            | 20.69 ± 5.13**       | 37.44±10.48           | 27.44 ± 9.90**       | 1.44±0.51             | 0.94±0.48**          |

Compared with the corresponding values before administration, \*\*P < 0.01

**[00137]** Table 8-2 Rating of severity of disease based on CDR scores

| CDR scores | Number of improved cases<br>(improvement rate) |                                |  |
|------------|------------------------------------------------|--------------------------------|--|
|            | Before administration                          | After 6 months' administration |  |
| Moderate   | 7 patients                                     | 5(71.4%)                       |  |
| Mild       | 9 patients                                     | 6(66.7%)                       |  |

[00138] The data in Table 8-1 demonstrate that the medication treatment for 6 months significantly improved MMSE, ADAS cog and CDR scores, and as compared with the baseline scores before administration, the differences were statistical significant ( $P < 0.01$ ), indicating that the medicament significantly improved cognitive function in AD patients. The data in Table 8-2 demonstrate that, according to the CDR scores, 5 of 7 patients of moderate AD after taking medicine for 6 months turned to mild, showing an improvement rate of 71.4% and 6 of 9 patients of mild AD after taking medicine for 6 months turned to suspected dementia, showing an improvement rate of 66.7%.

10 [00139] Table 9 Effect on NPI and ADL scores

| Group              | NPI                   |                      | ADL                   |                      |
|--------------------|-----------------------|----------------------|-----------------------|----------------------|
|                    | Before administration | After administration | Before administration | After administration |
| Experimental group | 2.50±3.03             | 0.56±1.75*           | 31.62±6.60            | 25.81±5.73**         |

Compared with the corresponding values before administration, \* $P < 0.05$ , \*\* $P < 0.01$

[00140] The data in Table 9 clearly demonstrate that patients after taking medicines for 6 months had obviously improved NPI and ADL, and compared with the baseline scores before administration, the differences were statistically significant ( $P < 0.01\sim 0.05$ ), indicating that the medicament significantly improved nerve and mental conditions and daily life ability of AD patients.

## Claims

What is claimed is:

1. A pharmaceutical composition for use in treating or preventing senile dementia, characterized in that the active ingredients of the pharmaceutical composition are prepared  
5 from raw medicinal materials consisting of 20-50 parts by weight of Epimedii Folium, 15-55 parts by weight of Poria and 10-55 parts by weight of Acanthopanax.
2. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in claim 1, characterized in that the active ingredients of the pharmaceutical composition are prepared from raw medicinal materials consisting of 20-  
10 30 parts by weight of Epimedii Folium, 20-45 parts by weight of Poria and 20-55 parts by weight of Acanthopanax.
3. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in claim 2, characterized in that the active ingredients of the pharmaceutical composition are prepared from raw medicinal materials consisting of 30  
15 parts by weight of Epimedii Folium, 30 parts by weight of Poria and 35 parts by weight of Acanthopanax.
4. A pharmaceutical composition for use in treating or preventing senile dementia, characterized in that the active ingredients of the pharmaceutical composition are prepared from raw medicinal materials consisting of 20-50 parts by weight of Epimedii Folium, 15-  
20 50 parts by weight of Poria, 10-50 parts by weight of Acanthopanax and 6-15 parts by weight of Anemarrhenae Rhizoma.
5. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in claim 4, characterized in that the active ingredients of the pharmaceutical composition are prepared from raw medicinal materials consisting of 20-  
25 30 parts by weight of Epimedii Folium, 20-30 parts by weight of Poria, 25-50 parts by weight of Acanthopanax, and 10-15 parts by weight of Anemarrhenae Rhizoma.

6. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in claim 5, characterized in that the active ingredients of the pharmaceutical composition are prepared from raw medicinal materials consisting of 30 parts by weight of Epimedii Folium, 30 parts by weight of Poria, 25 parts by weight of Acanthopanax and 15 parts by weight of Anemarrhenae Rhizoma.

7. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in any one of claims 1-6, characterized in that said Poria is replaced by Poria cum Radix Pini or Polyporus.

8. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in any one of claims 1-6, characterized in that said Acanthopanax is replaced by Acanthopanaxis cortex or Acanthopanaxis folium.

9. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in any one of claims 1-6, characterized in that said Poria is processed by the following steps of: extracting said weight parts of Poria with water 2-3 times each for 1-3 hours, wherein the first extraction is carried out with water that is 6-10 times the weight of Poria, and the second and third extractions each are carried out with water that is 4-8 times the weight of Poria; and filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; preferably by the following steps of extracting said weight parts of Poria with water 3 times each for 1 hour, wherein the first extraction is carried out with water that is 8 times the weight of Poria, and the second and third extractions each are carried out with water that is 6 times the weight of Poria; and filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure.

10. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in any one of claims 1-6, characterized in that said Epimedii Folium is processed by the following steps of: extracting said weight parts of Epimedii Folium with 30-70% ethanol solution 2-3 times each for 1-3 hours, wherein the first extraction is carried out with 30-70% ethanol solution that is 7-16 times the weight of Epimedii Folium, and the second and third extractions each are carried out with 30-70% ethanol solution that is 4-12 times the weight of Epimedii Folium; filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract; preferably by the following steps of extracting said weight parts of Epimedii Folium with

50% ethanol solution 3 times each for 1 hour, wherein the first extraction is carried out with 50% ethanol solution that is 9 times the weight of *Epimedii Folium*, the second extraction is carried out with 50% ethanol solution that is 7 times the weight of *Epimedii Folium* and the third extraction is carried out with 50% ethanol solution that is 5 times the weight of *Epimedii Folium*; and filtering the resulting extract solution and recovering ethanol under reduced pressure followed by concentrating it into a dry extract.

11. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in any one of claims 1-6, characterized in that said *Acanthopanax* is processed by the following steps of extracting said weight parts of *Acanthopanax* with water 2-3 times each for 1-3 hours, wherein the first extraction is carried out with water that is 6-10 times the weight of *Acanthopanax*; and the second and third extractions each are carried out with water that is 4-8 times the weight of *Acanthopanax*; and filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure; preferably by the following steps of extracting said weight parts of *Acanthopanax* with water 3 times each for 1 hour, wherein the first extraction is carried out with water that is 8 times the weight of *Acanthopanax*; and the second and third extractions each are carried out with water that is 6 times the weight of *Acanthopanax*; and filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure.

12. The pharmaceutical composition for use in treating or preventing senile dementia as claimed in any one of claims 4-6, characterized in that said *Anemarrhenae Rhizoma* is processed by the following steps of placing said weight parts of *Anemarrhenae Rhizoma* into water that is 6-10 times the weight of *Anemarrhenae Rhizoma*, heating the water until it boils and then decocting *Anemarrhenae Rhizoma* for 2-4 hours, removing and keeping the supernatant liquid, repeating the above process on the resulting residue again, and then filtering the combined extract solution followed by concentrating it into a dry extract; preferably by the following steps of placing said weight parts of *Anemarrhenae Rhizoma* into water that is 6 times the weight of *Anemarrhenae Rhizoma*, heating the water until it boils and then decocting *Anemarrhenae Rhizoma* for 2 hours, removing and keeping the supernatant, repeating the above process on the resulting residue again, and then filtering the combined extract solution followed by concentrating it into a dry extract.

13. A process for the preparation of the pharmaceutical composition for use in treating or preventing senile dementia as defined in claim 1-3, characterized in that the process comprises:

extracting said weight parts of Poria and said weight parts of Acanthopanax, separately or in combination, with water 2-3 times each for 1-3 hours, wherein the first extraction is carried out with water that is 6-10 times by weight, and the second and third extractions each are carried out with water that is 4-8 times by weight, respectively; and filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure;

preferably extracting said weight parts of Poria and said weight parts of Acanthopanax, separately or in combination, with water 3 times each for 1 hour, wherein the first extraction is carried out with water that is 8 times by weight, and the second and third extractions each are carried out with water that is 6 times by weight; and filtering the resulting extract solution and concentrating it into a dry extract under reduced pressure;

extracting said weight parts of Epimedii Folium with 30-70% ethanol solution 2-3 times each for 1-3 hours, wherein the first extraction is carried out with 30-70% ethanol solution that is 7-16 times the weight of Epimedii Folium, and the second and third extractions each carried out with 30-70% ethanol solution that is 4-12 times the weight of Epimedii Folium; filtering the resulting extract and recovering ethanol under reduced pressure followed by concentrating it into a dry extract; preferably extracting said weight parts of

Epimedii Folium with 50% ethanol solution 3 times each for 1 hour, wherein the first extraction is carried out with 50% ethanol solution that is 9 times the weight of Epimedii Folium, the second extraction is carried out with 50% ethanol solution that is 7 times the weight of Epimedii Folium and the third extraction is carried out with 50% ethanol solution that is 5 times the weight of Epimedii Folium; filtering the resulting extract and

recovering ethanol under reduced pressure followed by concentrating it into a dry extract; and

mixing the above two resulting extracts uniformly to obtain said pharmaceutical composition.

14. A process for the preparation of the pharmaceutical composition for use in treating or preventing senile dementia as defined in any one of claims 4-6, characterized in that the process comprises:

extracting said weight parts of *Poria* and said weight parts of *Acanthopanax*, separately or in combination, with water 2-3 times each for 1-3 hours, wherein the first extraction is carried out with water that is 6-10 times by weight, and the second and third extractions

each are carried out with water that is 4-8 times by weight; and filtering the resulting

5 extract and concentrating it into a dry extract under reduced pressure; preferably extracting said weight parts of *Poria* and said weight parts of *Acanthopanax*, separately or in combination, with water 3 times each for 1 hour, wherein the first extraction is carried out with water that is 8 times by weight, and the second and third extractions each are carried out with water that is 6 times by weight; and filtering the resulting extract and

10 concentrating it into a dry extract under reduced pressure;

extracting said weight parts of *Epimedii Folium* with 30-70% ethanol solution 2-3 times each for 1-3 hours, wherein the first extraction is carried out with 30-70% ethanol solution that is 7-16 times the weight of *Epimedii Folium*, and the second and third extractions each are carried out with 30-70% ethanol solution that is 4-12 times the weight of

15 *Epimedii Folium*; filtering the resulting extract and recovering ethanol under reduced pressure followed by concentrating it into a dry extract; preferably extracting said weight parts of *Epimedii Folium* with 50% ethanol solution 3 times each for 1 hour, wherein the first extraction is carried out with 50% ethanol solution that is 9 times the weight of *Epimedii Folium*, the second extraction is carried out with 50% ethanol solution that is 7

20 times the weight of *Epimedii Folium* and the third extraction is carried out with 50% ethanol solution that is 5 times the weight of *Epimedii Folium*; filtering the resulting extract and recovering ethanol under reduced pressure followed by concentrating it into a dry extract;

placing said weight parts of *Anemarrhenae Rhizoma* into water that is 6-10 times the weight of *Anemarrhenae Rhizoma*, heating the water until it boils and then decocting *Anemarrhenae Rhizoma* for 2-4 hours, removing and keeping the supernatant, repeating the above process on the resulting residue again, and filtering the combined extract solution followed by concentrating it into a dry extract; preferably placing said weight parts of *Anemarrhenae Rhizoma* into water that is 6 times the weight of *Anemarrhenae*

30 *Rhizoma*, heating the water until it boils and then decocting *Anemarrhenae Rhizoma* for 2 hours, removing and keeping the supernatant, repeating the above process on the resulting

residue, and filtering the combined extract solution followed by concentrating it into a dry extract; and

mixing the above three resulting extracts uniformly to obtain said pharmaceutical composition.