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(72) Inventor; and

(71) Applicant : BILGIC, Mahmut [—/TR]; Yildiz Teknik
Universitesi Davutpasa Kampus Teknoloji, Gelistirme Bol-
gesi D Blok, 34220 Esenler-Istanbul (TR).

(74) Agent: ISCANI, Burcu; Yildiz Teknik Universitesi Dav-
utpasa Kampus Teknoloji, Gelistirme Bolgesi D Blok,
34220 Esenler- Istanbul (TR).

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(54) Title: PHARMACEUTICAL FORMULATIONS COMPRISING ISOFLAVONE

(57) Abstract: The present invention relates to formulations comprising at least one component belonging the group of isoflavones,
preparation methods and area of use thereof.



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PHARMACEUTICAL FORMULATIONS COMPRISING ISOFLAVONE

The present invention relates to water soluble formulations comprising at least one component belonging to the group of isoflavones, preparation methods and area of use thereof.

The Prior Art

5 Plant originated estrogens or phenolic compounds having estrogenic effect are called phytoestrogens. Phytoestrogens which have estrogenic effect in variable degrees and which are similar to natural estrogens in terms of both structure and shape exert their effects directly through binding to receptors by competing with natural estrogens in the organism. In addition, phytoestrogens can change the efficiency of some enzymes having a role in estrogen
10 metabolism.

Phytoestrogens are divided into different subclasses according to different resources. These can be listed under four different classes in total: isoflavones, lignans, coumestans and stilbenes. Each class is composed of different compounds in itself and resources of these compounds in diet are different from each other.

15 Daidzein and genistein are the compounds belonging to the class of isoflavones of flavanoids in plants. Furthermore, since isoflavones are plant originated compounds having an estrogen-like biological activity, they are also called phytoestrogens. Isoflavons are comprised particularly in soybean and soy products. Soybean comprises 84 mg daidzein and 111 mg genistein per 100 g of soybean.

20 In recent years, many studies have been conducted on potential protective effects of isoflavons against cardiovascular diseases, menopause symptoms, bone diseases such as osteoporosis, osteomalacia and fibrous osteodystrophy and cancers associated with hormones (breast and prostate cancer).

Use of isoflavones decreases severity and frequency of vasomotor symptoms arising along
25 with the movement of contraction and dilatation of blood vessels associated with menopause. Particularly, the vessels close to skin surface play an important role particularly in regulating body temperature.

In the studies, it has been found that use of 60 mg soy protein per day alleviates vasomotor symptoms at the rate of 50%; 70 mg soy protein alleviates vasomotor symptoms at the rate of
30 61%.

As a result of 38 clinical studies conducted, it has been seen that total cholesterol decreased at the rate of 9.3%, LDL cholesterol (low density lipoprotein) was reduced at the rate of 12.9% and plasma triglycerides was reduced at the rate of 10.5% in the people who were administered soy protein isolates.

- 5 One of the important reasons for preferring phytoestrogens acting like estrogen in treatment of many diseases mentioned above is that use of estrogen hormone directly in said treatments results in various side effects such as increase in risk of thrombosis and breast cancer, and weight gain.

- 10 Soybean, soy tofu, soy milk, soy sauce, soy mince can be listed among soy products that can be taken in daily diet. However, use of these products is closely associated with food habits of people and the region where they live. Soy products are not included in daily diet of most of the people.

- However, as explained above, there is need for new approaches associated with soy products which appeal to a wide patient profile used in treatment and/or prevention of many diseases
15 from heart diseases to menopause symptoms; from osteoporosis to prostate cancer.

- In line with this requirement, tablet formulations comprising sufficient amount of genistein and used as daily food supplement are produced in the prior art. However, tablet dosage forms are not convenient for use since they pose swallowing problems particularly in geriatric patient group. Problem and solution relations existing in the prior art generally aim at
20 combining the compound with other daily supplements. However, the compound has a considerably sensitive nature and is considerably hygroscopic and low-soluble as well. This situation makes the selection of excipients, production method and dosage form critical for production of the formulations comprising genistein. When the compound is desired to be produced particularly in water soluble dosage forms, special solutions are required.

- 25 The European patent numbered EP1392337 discloses formulations comprising a dry plant extract such as genistein. This patent discloses that formulations comprising such an active agent are not preferred in soluble form due to their instability against acids and low solubility in water. Therefore, the formulations according to the patent are produced in a solid dosage form, preferably in tablet or capsule form. However, solid dosage forms cause swallowing
30 problems particularly for geriatric patients as mentioned before.

Therefore, there is need for new formulations whose solubility characteristic is improved for formulations comprising genistein, which can remain stable for a long time, which are easy to use and which appeal to a wide patient profile.

As a result of the studies he conducted, the inventor has achieved to produce the formulations comprising genistein, a compound belonging to the group of isoflavones, in water soluble form and without causing a solubility and/or stability problem in order to be used in treatment and/or prevention of bone diseases which are generally seen in postmenopausal period such as particularly osteoporosis, osteomalacia and fibrous osteodystrophy.

Detailed Description of the Invention

10 The present invention discloses stable genistein formulations which comprise efficient amounts of genistein and are suitable for oral use. Said formulations are in water soluble form.

The formulations of the present invention comprises genistein at least at the ratio of 1%, preferably in the range of 1 to 20%, more preferably in the range of 0.1 to 10% in proportion to total weight.

The formulations of the present invention comprise genistein in the range of 1 to 200 mg, preferably in the range of 1 to 100 mg per unit dosage form.

The formulations of the present invention do not comprise a pharmaceutical excipient in order to enhance solubility. On the other hand, these formulations dissolve by forming a clear solution between 0.5 and 5 minutes, preferably between 0.5 and 3 minutes, more preferably between 0.5 to 2 minutes after they are put in water at room temperature.

This unexpected effect arises from the use of lactose in monohydrate form as the diluent in the formulations. The inventor has produced the formulations in water soluble form comprising genistein, which has a rather low solubility in water, along with lactose monohydrate. Surprisingly, lactose monohydrate which causes incompatibility with many substances has not caused any degradation in the formulations of the present invention.

The formulations of the present invention comprise lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight.

Use of lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight in the formulations of the present invention has surprisingly caused an improvement in solubility of the end product.

5 In other words, the present invention relates to water soluble genistein formulations comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight.

An advantage of the formulations of the present invention is that they appeal to a wide patient profile since they are in water soluble form. The water soluble formulations of the present invention are preferably effervescent formulations.

10 The formulations of the present invention can comprise at least one other pharmaceutically acceptable excipient in addition to genistein and lactose monohydrate. The pharmaceutically acceptable excipients which are probable to be comprised in the formulations of the present invention can be selected from disintegrants, sweeteners, effervescent acids, effervescent bases, binders, lubricants, flavouring agents, colouring agents, pH regulators, basic substances
15 or combinations thereof.

The disintegrants that can be used in water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight can be selected from a group comprising highly dispersive polymers, for instance cross linked hydroxypropyl cellulose, polyvinylpyrrolidone, high-
20 molecular weighted polymers, microcrystalline cellulose, sodium starch glycolate, povidone, alginic acid, sodium alginate or combinations thereof.

The pharmaceutically acceptable effervescent acid that can be used in water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight can be selected from a group
25 comprising citric acid, tartaric acid, malic acid, fumaric acid, monosodium citrate and/or pharmaceutically acceptable salts, hydrates, anhydrides or a combination thereof.

The formulations of the present invention comprise at least one pharmaceutically acceptable effervescent acid in the range of 1 to 90% by weight, preferably in the range of 1 to 80% by weight, more preferably in the range of 1 to 70% by weight.

Pharmaceutically acceptable effervescent bases that can be used in water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight can be selected from a group comprising sodium, potassium and calcium carbonates, bicarbonates and/or sodium glycine
5 carbonate or a combination thereof. The formulations of the present invention comprise at least one pharmaceutically acceptable effervescent base in the range of 1 to 80% by weight, preferably in the range of 1 to 60% by weight, more preferably in the range of 1 to 50% by weight.

The binders that can be used in water soluble genistein formulations of the present invention
10 comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight can be selected from a group comprising potato, wheat or corn starch; microcrystalline cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose; hydroxypropyl methyl cellulose and polyvinylpyrrolidone or combinations thereof.

It is important to prevent active agent-excipient and excipient-excipient interactions and
15 ensure stability of the formulation in the formulations of the present invention comprising genistein as well as providing the required solubility characteristics. Therefore, it is required to select the type and amount of the excipients comprised in the formulations meticulously.

According to this, water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to
20 5% by weight comprise at least one pharmaceutically acceptable binder in the range of 1 to 5% by weight.

The ratio of the binder to lactose monohydrate comprised in the formulations of the present invention is in the range of 0.1 to 5 by weight, preferably in the range of 0.1 to 4 by weight, more preferably in the range of 0.1 to 3 by weight.

25 A possible incompatibility and a possible degradation that can arise from the use of lactose monohydrate and binder together are prevented by the use of two excipients at the given rates.

The binder which is preferred in water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight is polyvinylpyrrolidone.

The sweeteners that can be used in water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight can be selected from a group comprising aspartame, dextrose, fructose, sucralose, sodium cyclamate, mannitol, maltose, sorbitol, saccharin and/or pharmaceutically acceptable salts or combinations thereof. The formulations of the present invention comprise at least one pharmaceutically acceptable sweetener in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight, more preferably in the range of 0.1 to 3 % by weight.

The flavouring agents that can be used in water soluble genistein formulations of the present invention comprising lactose monohydrate in the range of 0.1 to 10% by weight, preferably in the range of 0.1 to 5% by weight can have banana, strawberry, lemon, orange, peach, vanilla flavours or a similar natural fruit flavour or an aromatic plant flavour.

Another advantage of the formulations of the present invention is that a solubility and/or stability enhancing substance are not used in the formulations.

The formulations of the present invention can be produced by a production method in the prior art, for instance wet granulation, dry granulation and/or dry blending.

A method preferred for the formulations of the present invention comprising genistein is dry blending method.

Another method preferred for the formulations of the present invention comprising genistein is wet granulation method.

The formulations of the present invention can optionally be used with at least one other active agent in combined form.

The term "other active agent" mentioned herein refers to various vitamins and/or minerals required for human body.

Dosage forms can be taken separately, together or sequentially; though they can also be taken by combining genistein with the other active agent or agents in a single dosage form for combined treatment.

In other words, the active agents can be together with at least one pharmaceutically acceptable excipient in a single formulation, though the active agents can also be formulated separately

together with at least one pharmaceutically acceptable excipient in the formulations comprising genistein and at least one other active agent for combined therapy.

Different formulations obtained can be combined in a single dosage form or can be prepared in the manner that they are in separate dosage forms. In the case that the formulations are in
5 separate dosage forms, said dosage forms can be same or different. The other active agent or agents that can be used together with genistein in combined therapy can be minerals such as calcium, potassium, magnesium, iron, sodium, zinc; vitamins such as vitamin A, B vitamins such as B1, B12, B6 and/or folic acid, vitamin C, vitamin D, vitamin E. One or two of other
10 active agents listed above can be combined with genistein in combined treatment. In other words, the present invention comprises binary and ternary combinations of genistein with the other active agents explained above.

The other active agent or agents that can be used in combined therapy can be produced together with genistein and by the same production method, though they can also be prepared by producing the active agent formulations separately and then by combining them.

15 The examples of the formulation of the present invention are below. These examples are given in order to elucidate the subject of the present invention, yet the present invention is not limited to these examples.

EXAMPLES**1. Effervescent formulation comprising genistein**

Content	(%) of amount in unit dose
Genistein	1.50
Effervescent couple	75.00
Lactose Monohydrate	3.00
Binder	1.50
Sweetener	1.00
At least one other excipient	18.00
Total	100

The formulation given above is prepared by dry blending method and is preferably
 5 compressed into tablets by sending the formulation to tablet compression machine.

2. Effervescent formulation comprising Genistein and Calcium

Content	(%) of amount in unit dose
Genistein	1.00
Calcium Carbonate	37.00
Effervescent acid	35.00
Effervescent base	20.00
Lactose Monohydrate	3.00
Binder	1.50
Sweetener	1.00
Lubricant	1.50
Total	100

3. Effervescent formulation comprising Genistein, Calcium and Vitamin D

Content	(%) of amount in unit dose
Genistein	0.50
Calcium Carbonate	37.00
Vitamin D	0.10
Effervescent acid	35.00
Effervescent base	20.00
Lactose Monohydrate	3.00
Binder	1.50
Sweetener	0.90
Lubricant	2.00
Total	100

CLAIMS

1. A pharmaceutical formulation comprising genistein, characterized in that said formulation is in water soluble form.
2. The pharmaceutical formulation according to claim 1, characterized in that said
5 formulations comprise lactose monohydrate.
3. The pharmaceutical formulation according to claim 2, characterized in that said formulation comprises lactose monohydrate in the range of 0.1 to 10% by weight.
4. The pharmaceutical formulation according to claim 3, characterized in that said formulation comprises lactose monohydrate in the range of 0.1 to 5% by weight.
- 10 5. The pharmaceutical formulation according to any preceding claims, characterized in that said formulation comprises genistein in the range of 0.1 to 10% by weight.
6. The pharmaceutical formulation according to claim 5, characterized in that said formulation comprises genistein in the range of 0.1 to 5% by weight.
7. The formulation according to any preceding claims, characterized in that said
15 formulation is in effervescent form.
8. The pharmaceutical formulation according to any preceding claims, characterized in that said formulation comprises at least one pharmaceutically acceptable binder selected from a group comprising potato, wheat or corn starch, microcrystalline cellulose, hydroxypropyl cellulose, hydroxyethyl cellulose, hydroxypropyl methyl
20 cellulose and polyvinylpyrrolidone or combinations thereof.
9. The pharmaceutical formulation according to claim 8, characterized in that the pharmaceutical formulations comprise at least one binder in the range of 1-5% by weight.
10. The pharmaceutical formulation according to claims 2-9, characterized in that the
25 ratio of the binder to lactose monohydrate comprised in the formulations is in the range of 0.1 to 5 by weight.
11. The pharmaceutical formulation according to claim 10, characterized in that the ratio of the binder to lactose monohydrate comprised in the formulations is in the range of 0.1 to 4 by weight.
- 30 12. The pharmaceutical formulation according to claim 11, characterized in that the ratio of the binder to lactose monohydrate comprised in the formulations is in the range of 0.1 to 3 by weight.
13. The pharmaceutical formulation according to claims 8-12, characterized in that the binder comprised in the formulations is polyvinylpyrrolidone.

14. The pharmaceutical formulation according to claim 7, characterized in that said formulation comprises at least one pharmaceutically acceptable effervescent acid in the range of 1 to 90% by weight.
15. The pharmaceutical formulation according to claim 14, characterized in that effervescent acid used in the formulations is selected from a group comprising citric acid, tartaric acid, malic acid, fumaric acid, monosodium citrate, tartaric acid and/or pharmaceutically acceptable salts, hydrates, anhydrides or a combination thereof.
16. The formulation according to claim 7, characterized in that said formulation comprises at least one pharmaceutically acceptable effervescent base in the range of 1 to 80% by weight.
17. The formulation according to claim 16, characterized in that the effervescent base used in the formulations is selected from a group comprising sodium, potassium, and calcium carbonates, bicarbonates and/or sodium glycine carbonate or a combination thereof.
18. The formulation according to any preceding claims, characterized in that said formulations are used with at least one other active agent in combined form.
19. The formulation according to claim 18, characterized in that the active agents are taken separately, together or sequentially or by combining genistein with at least one other active agent in a single dosage form in the formulations comprising genistein and at least one other active agent.
20. The formulation according to claims 18-19, characterized in that other active agent or agents are at least one vitamin and/or at least one mineral.
21. The formulation according to claims 18-20, characterized in that the other active agent or agents is selected from a group comprising minerals such as calcium, potassium, magnesium, iron, sodium, zinc; vitamins such as vitamin A, B vitamins such as B1, B12, B6 and/or folic acid, vitamin C, vitamin D, vitamin E.
22. The formulation according to claim 1, characterized in that said formulation is used in treatment and/or prevention of bone diseases such as osteoporosis, osteomalacia and fibrous osteodystrophy.

INTERNATIONAL SEARCH REPORT

International application No

PCT/TR2012/000119

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K9/20 A61K9/46 A61K31/353
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, BIOSIS, EMBASE, WPI Data, FSTA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 200545 Thomson Scientific, London, GB; AN 2005-436088 XP002691627, -& CN 1 589 786 A (ZHENGZHOU BOKAI MEDICINE HEALTH FOOD CO) 9 March 2005 (2005-03-09) abstract claims examples 1, 2	1,5-9, 13-22
X	----- WO 2010/097643 A1 (NOVATECH ISTRAZIVANJE D O O [HR]; LELAS ANTONIO [HR]; CEPANEC IVICA [H] 2 September 2010 (2010-09-02) pages 9-10 example 1 claims 1-5 -----	1,2,5, 8-13, 18-20 2-4
Y	----- -/-	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

van de Wetering, P

INTERNATIONAL SEARCH REPORT

International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/103181 A1 (SEN HIMADRI [IN] ET AL) 1 August 2002 (2002-08-01) examples 2-6, 8-10 -----	2-4
X,P	WO 2012/002918 A1 (BILGIC MAHMUT [TR]) 5 January 2012 (2012-01-05) page 3, line 3 - page 5, line 5 example 1 -----	1,7,8, 13-22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/TR2012/000119

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7, 10-22(completely); 8, 9(partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7, 10-22(completely); 8, 9(partially)

A pharmaceutical formulation comprising genistein characterised in that said formulation is in water soluble form and comprises lactose monohydrate.

2. claims: 8, 9(partially)

A pharmaceutical formulation comprising genistein characterised in that said formulation is in water soluble form and comprises potato, wheat or corn starch as binder.

3. claims: 8, 9(partially)

A pharmaceutical formulation comprising genistein characterised in that said formulation is in water soluble form and comprises microcrystalline cellulose as binder.

4. claims: 8, 9(partially)

A pharmaceutical formulation comprising genistein characterised in that said formulation is in water soluble form and comprises hydroxypropyl cellulose as binder.

5. claims: 8, 9(partially)

A pharmaceutical formulation comprising genistein characterised in that said formulation is in water soluble form and comprises hydroxyethyl cellulose as binder.

6. claims: 8, 9(partially)

A pharmaceutical formulation comprising genistein characterised in that said formulation is in water soluble form and comprises hydroxypropyl methyl cellulose as binder.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/TR2012/000119

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
CN 1589786	A	09-03-2005	NONE	
WO 2010097643	A1	02-09-2010	NONE	
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