

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
6 May 2005 (06.05.2005)

PCT

(10) International Publication Number
WO 2005/039611 A1

(51) International Patent Classification⁷: **A61K 35/78**

(21) International Application Number:

PCT/IB2003/004807

(22) International Filing Date: 28 October 2003 (28.10.2003)

(25) Filing Language: English

(26) Publication Language: English

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(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,

RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD,

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(54) Title: A NOVEL HERBAL COMPOSITION FOR THE TREATMENT OF GASTRIC ULCER

(57) Abstract: The present invention provides a synergistic herbal composition for the treatment of gastric ulcer, said composition essentially comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparum roxburghicinum* and optionally, powdered plant parts of *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes* along with one or more pharmaceutically acceptable additives/carriers, a process for preparing said composition and a method for treating gastric ulcer using said composition.

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- CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- Published:**
- with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A NOVEL HERBAL COMPOSITION FOR THE TREATMENT OF GASTRIC ULCER

Field of the Invention

- 5 The present invention relates to a novel synergistic herbal composition for the treatment of gastric ulcer. The present invention also relates to a method for the preparation of the composition. The present invention further relates to a process for the treatment of gastric ulcer using the composition.

Background and prior art to the Invention

- 10 Various theories have been proposed with respect to a cause of ulcer in human. In particular, it has been elucidated that stress, taking of non-steroidal anti-inflammatory drugs for curing rheumatic diseases, and the like are closely related to ulcer formation, mainly due to relatively excess gastric or duodenal acid secretion. Accordingly it is important to suppress the acid secretion in order to prevent ulcer formation and to cure it.
- 15 On the other hand it has been considered that *Helicobacter pylori*, which is a rod normally existing in stomach, generates ammonia due to its strong urease activity, thereby inducing ulcer. Since, it persistently lives within mucus and mucosa, it becomes the greatest cause for recurrence of ulcer. Accordingly, it has been considered that the recurrence of ulcer can be prevented, if this bacterium is sterilized.
- 20 References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p 74-76, 155, published by Popular Prakashan Pvt. Ltd., Mumbai; K.R. Kirtikar in Indian Medicinal Plants (1975) Vol. 4, p 2505 published by Bishen Singh Mahendrapal Singh, Dehradun and P.K. Warrier in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 1, p 103 for the various medicinal properties of *Aloe barbadensis*.
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- 30 (1963) Series 1, No. 6, p. 48 published by Department of Pharmacognosy, University of Kerala, Trivandrum for the various medicinal properties of *Asperagus racemosus*. References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p 582 published by Popular Prakashan Pvt. Ltd., Mumbai; K.R. Kirtikar in Indian Medicinal Plants (1975) Vol. 1, p. 728 published by Bishen Singh Mahendrapal Singh,
- 35 Dehradun; P.K. Warrier in Indian Medicinal Plants- A compendium of 500 species (1994-

1996) Vol. 3, p 84, 86-87; The Wealth of India (1950-1980) Vol. 4, p. 152-153, published by Council of Scientific and Industrial Research; S.S. Handa in Indian Herbal Pharmacopeia (1998), p. 96, published by Regional Research Laboratory, Jammu and IDMA, Mumbai; Y.K. Sarin in Illustrated lanual of herbal drugs used in Ayurveda (1996),
5 p. 116, and The Ayurvedic Pharmacopoeia of India, Vol. 1, p. 128, published by Ministry of Health and Family Welfare, India for the various medicinal properties of *Glychyrrhiza glabra*.

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10 Medicinal Plants (1975) Vol. 3, p 1858-89 published by Bishen Singh Mahendrapal Singh, Dehradun; P.K. Warriar in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 5, p 104, and The Wealth of India (1950-1980) Vol. 9, p. 290, published by Council of Scientific and Industrial Research for the various medicinal properties of *Seaamum indicum*.

15 References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p 531, published by Popular Prakashan Pvt. Ltd., Mumbai; P.K. Warriar in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 3, p. 11-12, and K. Narayana Iyer and M. Kolammal in Pharmacognosy of Ayurvedic Drugs (1963) Series 1, No. 6, p. 1, published by Department of Pharmacognosy, University of Kerala, Trivandrum for the
20 various medicinal properties of *Evolvulus aisinodes*.

References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p822-825, published by Popular Prakashan Pvt. Ltd., Mumbai; K.R. Kirtikar in Indian Medicinal Plants (1975) Vol. 4, p. 2454, published by Bishen Singh Mahendrapal Singh, Dehradun, and P.K. Warriar in Indian Medicinal Plants- A compendium of 500 species (1994-1996)
25 Vol. 4, p 78 for the various medicinal properties of *Musa sapientum*.

References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p 1028-1030, published by Popular Prakashan Pvt. Ltd., Mumbai; P.K. Warriar in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 3, p. 299, published by
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30 Council of Scientific and Industrial Research; Y.K. Sarin in Illustrated lanual of herbal drugs used in Ayurveda (1996), p. 202, and The Ayurvedic Pharmacopoeia of India, Vol. 1, p. 3, published by Ministry of Health and Family Welfare, India for the various medicinal properties of *Trachyaparmum roxburghicum*.

References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p. 478, published by Popular Prakashan Pvt. Ltd., Mumbai; K.R. Kirtikar in Indian Medicinal Plants (1975) Vol. 2, p. 1479, published by Bishen Singh Mahendrapal Singh, Dehradun; P.K. Warrier in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 2, p. 368, published by orient Longman, Chennai; The Wealth of India (1950-1980) Vol. 3, p. 167, published by Council of Scientific and Industrial Research; Y.K. Sarin in Illustrated lanual of herbal drugs used in Ayurveda (1996), p. 290, and The Ayurvedic Pharmacopoeia of India, Vol. 1, p. 124, published by Ministry of Health and Family Welfare, India for the various medicinal properties of *Embelia ribes*.

- 10 References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p. 381-82, published by Popular Prakashan Pvt. Ltd., Mumbai; K.R. Kirtikar in Indian Medicinal Plants (1975) Vol. 2, p. 1225, published by Bishen Singh Mahendrapal Singh, Dehradun; P.K. Warrier in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 2, p. 184, published by orient Longman, Chennai, and The Wealth of India
15 (1950-1980) Vol. 3, p. 349, published by Council of Scientific and Industrial Research for the various medicinal properties of *Coriandrum sativum*.

Reference may be made to P.K. Warrier in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 2, p. 277, published by orient Longman for the various medicinal properties of *Cyclea peltate*.

- 20 References may be made to K.M. Nadkarni in Indian Materia Medica (1976) Vol. 1, p. 537, published by Popular Prakashan Pvt. Ltd., Mumbai; K.R. Kirtikar in Indian Medicinal Plants (1975) Vol. 2, p. 1217, published by Bishen Singh Mahendrapal Singh, Dehradun; P.K. Warrier in Indian Medicinal Plants- A compendium of 500 species (1994-1996) Vol. 3, p. 13, published by orient Longman, Chennai; Y.K. Sarin in Illustrated lanual of herbal
25 drugs used in Ayurveda (1996), p. 332, and The Ayurvedic Pharmacopoeia of India, p. 50, published by Ministry of Health and Family Welfare, India for the various medicinal properties of *Ferula asafoetida*.

The composition of the present invention should not be treated as an obvious one as none of the citations are able to provide all the advantages of the present invention. .

30 **Objects of the Invention**

The main object of the present invention is to provide a novel synergistic herbal composition for the treatment of gastric ulcer

Yet another object of the present invention is to provide a process for the preparation of the composition.

Still another object of the present invention is to provide a method for the treatment of gastric ulcer using the composition.

Summary of the Invention

The present invention provides a novel synergistic herbal composition for the treatment of gastric ulcer. Also, the present invention provides a process for the preparation of the composition. The present invention further provides a method for the treatment of gastric ulcer using said composition.

Detailed Description of the present Invention

In accordance with the first embodiment of the present invention, there is provided a synergistic herbal composition for the treatment of gastric ulcer, said composition essentially comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum* and optionally, powdered plant parts of *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes* along with one or more pharmaceutically acceptable additives/carriers.

In an embodiment of the present invention, the composition comprises powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers. This composition is hereafter referred to as HF3.

In another embodiment of the present invention, the composition comprises powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Evolvulus aisinodes* and *Ferula asafoetida* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers. This composition is hereafter referred to as HF4.

In yet another embodiment of the present invention, the composition comprises powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Evolvulus alsinodes*, *Ferula asafoetida*, *Coriandrum sativum*, *Cyclea peltate* and *Aloe barbadensis* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers. This composition is hereafter referred to as HF5.

In still another embodiment of the present invention, the composition comprises 5-13 wt. % of powdered plant parts of *Asperagus racemosus*, 5-12 wt. % of powdered plant parts of *Glycyrrhiza glabra*, 8-14 wt. % of powdered plant parts of *Seaamum indicum*, 7-14 wt. %

of powdered plant parts of *Musa sapientum*, 4-12 wt. % of powdered plant parts of *Trachyparum roxburghicinum*, 6-12 wt. % of powdered plant parts of *Aloe barbadensis*, 5-12 wt. % of powdered plant parts of *Evolvulus aisinodes*, 6-13 wt. % of powdered plant parts of *Cyclea peltate*, 9-14 wt. % of powdered plant parts of *Embelia ribes*, 7-14 wt. % of powdered plant parts of *Coriandrum sativum* and 8-13 wt. % of plant parts of *Ferula asafoetida*, optionally along with one or more pharmaceutically acceptable additives/carriers. This composition is hereafter referred to as HF2.

In one more embodiment of the present invention, the plant part of *Trachyparum roxburghicinum*, *Embelia ribes* and *Coriandrum sativum* is fruit.

10 In one another embodiment of the present invention, the plant part of *Cyclea peltate* and *Glycyrrhiza glabra* is root.

In a further embodiment of the present invention, the plant part of *Aloe barbadensis* is elio.

In a furthermore embodiment of the present invention, the plant part of *Asperagus racemosus* is tuber.

15 In an embodiment of the present invention, the plant part of *Seaamum indicum* is seed.

In another embodiment of the present invention, the plant part of *Musa sapientum* is unripe fruit.

In yet another embodiment of the present invention, the plant part of *Ferula asafoetida* is resin.

20 In accordance with the another embodiment of the present invention, there is provided a synergistic herbal composition for the treatment of gastric ulcer, said composition comprising equal proportions of 10 powdered plant parts selected from the group

comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*,
25 *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

----- In an embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*,
30 *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida* and *Aloe barbadensis*, optionally along with one or more pharmaceutically acceptable additives/carriers.

In another embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*,

Seaamum indicum, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

5 In yet another embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

10 In still another embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

15 In one more embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

20 In one another embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

25 In a further embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

30 In a further more embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

In an embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

In another embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

In yet another embodiment of the present invention, said composition comprises equal proportions of powdered plant parts of *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

In accordance with the second embodiment of the present invention, there is provided a process for the preparation of the novel synergistic herbal composition for the treatment of gastric ulcer, said process comprising the steps of powdering plant parts essentially selected from *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum* and optionally, selected from *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, mixing the aforesaid powdered plant parts to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.

In an embodiment of the present invention, said process comprises the steps of powdering plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum*, mixing the aforesaid plant parts in equal proportions to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.

In another embodiment of the present invention, said process comprises the steps of powdering plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Evolvulus aisinodes* and *Ferula*

asafoetida, mixing the aforesaid plant parts in equal proportions to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.

5 In yet another embodiment of the present invention, said process comprises steps of powdering plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Evolvulus alsinodes*, *Ferula asafoetida*, *Coriandrum sativum*, *Cyclea peltate* and *Aloe barbadensis*, mixing the aforesaid plant parts in equal proportions to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.

10 In still another embodiment of the present invention, said process comprises the steps of powdering and mixing 5-13 wt. % of plant parts of *Asperagus racemosus*, 5-12 wt. % of plant parts of *Glycyrrhiza glabra*, 8-14 wt. % of plant parts of *Seaamum indicum*, 7-14 wt. % of plant parts of *Musa sapientum*, 4-12 wt. % of plant parts of *Trachyparmum roxburghicinum*, 6-12 wt. % of plant parts of *Aloe barbadensis*, 5-12 wt. % of plant parts of *Evolvulus alsinodes*, 6-13 wt. % of plant parts of *Cyclea peltate* 9-14 wt. % of plant parts of *Embelia ribes*, 7-14 wt. % of plant parts of *Coriandrum sativum* and 8-13 wt. % of plant parts of *Ferula asafoetida* to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.

20 In one more embodiment of the present invention, the plant part of *Trachyparmum roxburghicinum*, *Embelia ribes* and *Coriandrum sativum* is fruit.

In one another embodiment of the present invention, the plant part of *Cyclea peltate* and *Glycyrrhiza glabra* is root.

In a further embodiment of the present invention, the plant part of *Aloe barbadensis* is elio.

25 In a furthermore embodiment of the present invention, the plant part of *Asperagus racemosus* is tuber.

In an embodiment of the present invention, the plant part of *Seaamum indicum* is seed.

In another embodiment of the present invention, the plant part of *Musa sapientum* is unripe fruit.

30 In yet another embodiment of the present invention, the plant part of *Ferula asafoetida* is resin.

In accordance with another object of the present invention, there is provided a method of treating gastric ulcer in a subject, said method comprising administering an effective amount of the synergistic herbal composition essentially comprising of powdered plant

parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum* and optionally, powdered plant parts of *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum* *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes* along with one or more pharmaceutically acceptable additives/carriers.

5 In an embodiment of the present invention, said method comprises administering an effective amount of the synergistic herbal composition comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.

10 In another embodiment of the present invention, said method comprises administering an effective amount of the synergistic herbal composition comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Evolvulus aisinodes* and *Ferula asafoetida* in equal proportions, optionally along with one or more pharmaceutically acceptable
15 additives/carriers.

In yet another embodiment of the present invention, said method comprises administering an effective amount of the synergistic herbal composition comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Evolvulus alsinodes*, *Ferula asafoetida*, *Coriandrum*
20 *sativum*, *Cyclea peltate* and *Aloe barbadensis* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.

In still another embodiment of the present invention, said method comprises administering an effective amount of the synergistic herbal composition comprising 5-13 wt. % of powdered plant parts of *Asperagus racemosus*, 5-12 wt. % of powdered plant parts of
25 *Glycyrrhiza glabra*, 8-14 wt. % of powdered plant parts of *Seaamum indicum*, 7-14 wt. % of powdered plant parts of *Musa sapientum*, 4-12 wt. % of powdered plant parts of *Trachyparmum roxburghicinum*, 6-12 wt. % of powdered plant parts of *Aloe barbadensis*,
--- 5-12 wt. % of powdered plant parts of *Evolvulus aisinodes*, 6-13 wt. % of powdered plant parts of *Cyclea peltate* 9-14 wt. % of powdered plant parts of *Embelia ribes*, 7-14 wt. % of powdered plant parts of *Coriandrum sativum* and 8-13 wt. % of plant parts of *Ferula*
30 *asafoetida* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.

In one more embodiment of the present invention, the subject is a mammal including human.

In one another embodiment of the present invention, the effective dosage of the composition per day is in the range of 5 to 15g.

In a further embodiment of the present invention, the composition can be in the form of tablets, capsules, syrup and any other conventional forms.

5 In a furthermore embodiment of the present invention, the composition is administered orally, intra-muscularly, and by any other conventional methods.

In an embodiment of the present invention, the composition may be used for therapeutic as well as prophylactic treatment of gastric ulcer.

10 In another embodiment of the present invention, the subject may be administered a bolus dose or a multiple dose.

In yet another embodiment of the present invention, wherein the composition HF2 showed more than 62% protection against cold restraint ulcer model.

In still another embodiment of the present invention, wherein the composition HF2 showed more than 30 % protection against aspirin induced ulcer model.

15 In one more embodiment of the present invention, wherein the composition HF2 reduced the length of hemorrhagic bands to 22.67 ± 4.69 (mm \pm SE) against alcohol induced gastric ulcer.

In one another embodiment of the present invention, wherein the composition HF2 has protection index greater than 80 against pyloric ligation induced ulcer.

20 **Brief Description of the Tables**

In the tables accompanying the specification,

Table 1 represents the effect of the herbal composition HF2 prepared in accordance with one of the embodiments of the present invention and a standard drug "Omeprazole" against Cold Restraint (at 4° C temp, for 2 hrs.) induced Ulcer (CRU).

25 **Table 2** represents the effect of the herbal composition HF2 prepared in accordance with one of the embodiments of the present invention and the standard drug "Omeprazole" against aspirin induced gastric ulcer.

Table 3 represents the effect of the herbal composition HF2 prepared in accordance with one of the embodiments of the present invention and the standard drug "Omeprazole" against alcohol induced gastric ulcer in rats.

30 **Table 4** represents the effect of the herbal composition HF2 prepared in accordance with one of the embodiments of the present invention and the standard drug "Omeprazole" against Histamine induced ulcer model.

Table 5 represents the effect of the herbal composition HF2 prepared in accordance with one of the embodiments of the present invention and a standard drug "Omeprazole" against Pyrolic ligation induced ulcer model.

Table 6 gives the composition of the Herbal composition HF2 prepared in accordance with one of the embodiments of the present invention.

Table 7 provides the antigastric ulcer activity of herbal compositions HF3, HF4 and HF5 prepared in accordance with the embodiments of the present invention against cold restrained ulcer model, pyloric ligation ulcer model and alcohol induced ulcer model.

Table 8 provides the results of the study conducted to evaluate the synergistic effect of the composition HF2.

Table 9 gives the composition of the Herbal compositions HF3, HF4 and HF5.

The invention is further described with respect to the following experiments which are given by way of illustration and therefore should not be construed to limit the scope of the invention in any manner.

Experimental protocol:

Invivo experiments:

The Applicants have carried out several experiments under different induced ulcer conditions and the effect of the herbal composition were studied and are tabulated herebelow. The effect of the herbal composition has been compared with respect to a known anti-ulcer drug "Omeprazole".

EXPERIMENT 1: EFFECT ON COLD RESTRAINT ULCERS (CRU) MODEL

METHOD: Adult rats of either sex, weighing 150-175 Gms were fasted for 24 hours with free access to water. The test drugs were administered 45 minutes before immobilizing the animals. The rats were immobilized in the restraint cage at 4°C in BOD incubator for 2 hrs and were sacrificed immediately after the restraint period. (According to the method of Senay and Levine 1967). The abdomen was cut opened; stomach was taken out and incised along the greater curvature to observe the gastric lesions with the help of Magnascope (5X magnification).

The following arbitrary scoring system was used to grade the severity and intensity of the lesions.

1. Shedding of epithelium = 10
2. Petechial and frank hemorrhages = 20
3. One or two ulcers = 30
4. More than two ulcers = 40
5. Perforated ulcers = 50

The presence of any of these lesions was considered as a positive ulcerogenic response which has been shown as percentage of rats showing gastric lesions.

The severity of ulcers is expressed in terms of ulcer index, which is the mean score of gastric lesions of all the rats in a group which is defined as:

$$\text{Ulcer Index (U.I.)} = U_s + U_p \times 10^{-1}$$

Where U_s = Mean severity of ulcer score and U_p - Percentage of animals with Ulcer incidences

The percentage protection is calculated as follows:

$$\text{Percentage protection} = (C - T / C) \times 100.$$

Wherein

C = Number of animals showing ulcer response in control group and

10 T = Number of animals showing ulcer response in test group.

The effect of the Herbal Composition of the present invention hereafter referred to as "HF2" against Cold Restraint Ulcer Model (CRU) is given in Table 1. The effect of the standard drug "Omeprazole" is also given in Table 1.

15 **TABLE 1: THE EFFECT OF THE HERBAL COMPOSITION "HF2" AND THE STANDARD DRUG "OMEPRAZOLE" AGAINST COLD RESTRAINT ULCER MODEL (CRU).**

Compounds and Doses	Ulcer severity (type of lesions) Scores (No. of rats showing lesions / No. of rats tested)					Mean severity of ulcer score	Percentage of ulcer incidence (No. of rats showing ulcer/total No. of rats used)	Ulcer index	Protection index
	10	20	30	40	50				
Control CRU	-	6/10	4/10	-	-	24	100 (10/10)	12.4	00
CRU+ HF2 (50mg/Kg, p.o.)	2/10	2/10	-	-	-	06	40 (4/10)	4.6	62.90
CRU+ Omeprazole (10 mg/Kg, p.o.)	3/10	2/10	-	-	-	07	50 (5/10)	5.7	54.03

INFERENCE: Omeprazole showed 54.03 % protection where as the composition HF2 showed 62.90%, protection against gastric ulcer. Thus it is clear that the composition HF2 provides significantly better protection against cold restraint ulcer model as compared to Omeprazole.

EXPERIMENT 2: EFFECT ON ASPIRIN INDUCED GASTRIC ULCER MODEL

METHOD: Gastric ulceration was induced by aspirin according to the method of Djahanguiri (1969). Aspirin (150 mg/Kg.) was administered per orally as a suspension in gum-acacia and the animal was sacrificed 5 hr. after the aspirin treatment and the ulcer index with protection index were calculated.

25 The results of the experiment is tabulated in Table 2.

The effect of the herbal composition HF2 and the standard drug "Omeprazole" against aspirin induced gastric ulcer is given in Table 2.

TABLE 2: THE EFFECT OF THE HERBAL COMPOSITION "HF2" AND THE STANDARD DRUG "OMEPRAZOLE" AGAINST ASPIRIN INDUCED GASTRIC ULCER

Compounds and Doses	Ulcer severity (type of lesions) Scores (No. of rats showing lesions / No. of rats tested)					Mean severity of ulcer score	Percentage of ulcer incidence (No. of rats showing ulcer/total No. of rats used)	Ulcer index	Protection index
	10	20	30	40	50				
Control Aspirin (150 mg/KG, p.o.)	-	2/6	4/6	-	-	26.6	100 (6/6)	12.66	00
Aspirin + HF 2 (100 mg/Kg, p.o.)	2/6	2/6	-	-	-	10.0	66.7(4/6)	7.67	39.41
Aspirin + Omeprazole (10 mg/Kg, p.o.)	2/6	2/6	-	-	-	10.0	66.7 (4/6)	7.67	39.41

5

INFERENCE: Both Omeprazole and the composition HF2 showed equal protection (39.41% protection) against aspirin induced ulcer model.

EXPERIMENT 3: EFFECT ON ALCOHOL INDUCED GASTRIC ULCERS IN RATS

10 **METHOD:** Adult rats of either sex were taken; weighing 150 - 175 grams were fasted for 24 hours with free access to water. The test drugs were administered (p.o.) 45 minutes before alcohol administration. 1 ml of chilled absolute alcohol was administered (p.o.) to the rats (According to Wittetal)³. Immediately after 1 hour, the animals were anesthetized, abdomen was cut opened stomach was taken out and incised along the greater curvature to observe the gastric lesions. The

15 ulcers are examined under the 5X magnification with the help of magnascope. Absolute ethanol lesions appears as blackish lesions grouped in patches of varying size, usually parallel to the major axis of the stomach. The lengths of the lesions are measured and summated to give a total lesion score, then calculated and expressed in percentage.

20 The effect of the herbal composition "HF2" and the standard drug "Omeprazole" against alcohol induced gastric ulcer in rats is given in Table 3.

TABLE 3: THE EFFECT OF THE HERBAL COMPOSITION "HF2" AND THE STANDARD DRUG "OMEPRAZOLE" AGAINST ALCOHOL INDUCED GASTRIC ULCER IN RATS

Compound	Length of hemorrhagic bands (mm \pm SE)
Ethanol control	73.5 \pm 1.5
HF 2 (100 mg/kg, p.o.) + Ethanol	22.67 \pm 4.69
Omeprazole (100 mg/kg, p.o.) + Ethanol	56.0 \pm 9.12

- 5 **INFERENCE:** The composition of the present invention showed significant protection against this model also. The protection provided by the composition of the present invention is better than Omeprazole.

EXPERIMENT 4: EFFECT ON HISTAMINE INDUCED ULCER MODEL

- 10 **METHOD:** Animals were fasted for 24 hours with access to water. The drug was given orally 1 hour prior to the histamine administration. Histamine was administered in a dose of 0.25 mg/Kg, i.m. at 30 minutes interval -for 7 times and it induced 100 % duodenal ulceration in guinea pig (According to the method of Watt and Eagleton 1964)⁴. The animals were sacrificed after half an hour of last injection under ether anesthesia. The stomach along
15 with duodenum was removed washed thoroughly and examined for the lesions and ulcer index with protection index was calculated. The results of the experiment are tabulated in Table 4. The effect of the herbal composition "HF2" and the standard drug "Omeprazole" against Histamine induced ulcer model is given in Table 4.

EXPERIMENT 5: EFFECT ON PYLORIC LIGATION INDUCED ULCER MODEL

- 20 **METHOD:** Animals were fasted for 24 hours in the raised mesh bottom cages to prevent coprophagia and were allowed free access to water. The control group of rats was feed with the vehicle and the experimental groups with their respective drugs 45 minutes prior to the ligation. The animal was anesthetized, abdomen was cut opened under xiphoid process, and the pyloric portion of the stomach was slightly lifted and ligated avoiding any damage to the adjacent blood vessels
25 (According to the method of Shay et al. 1945). The animals were stitched and kept for 4 hours with free access to water. After 4 hours the animals were sacrificed under ether anesthesia and the stomach was dissected out incised along the greater curvature. The stomach was washed thoroughly and the ulcer index was scored as per in other ulcer models. The results of the experiment are tabulated in Table 5.
- 30 The effect of the herbal composition "HF2" and the standard drug "Omeprazole" against Pyloric ligation induced ulcer model is given in Table 5.

TABLE 4: THE EFFECT OF THE HERBAL COMPOSITION "HF2" AND THE STANDARD DRUG "OMEPRAZOLE" AGAINST HISTAMINE INDUCED ULCER MODEL

Groups and doses of compounds	Ulcer severity (type of lesions) Scores (No. Guinea pig showing lesions / No. of Guinea pig tested)					Mean severity of ulcer score	Percentage of ulcer incidence (No. of animals showing ulcer/total No. of animals used)	Ulcer index	% Protection	Volume of gastric fluid (mL)
	10	20	30	40	50					
Ulcer Control Histamine (0.25mg/Kg,i.m.)x7	-	-	1/3	2/3	-	36.6	100 (3/3)	13.66	00	4.33 ±1.01
Histamine + HF2 (50 mg/Kg, p.o.)	-	-	1/3	-	-	10.0	33.3(1/3)	4.33	68.3	1.60 ± 0.7
Histamine + Omeprazole (10 mg/kg, p.o.)	-	1/3	-	-	-	6.66	33.3 (1/3)	3.99	70.79	1.0 ± 0.2

INFERENCE: In this model, Omeprazole showed 70.79% protection whereas the composition HF2 showed 68.3% protection. In comparison, the composition HF2 provides more or less equal protection.

TABLE 5: EFFECT OF OMEPRAZOLE AND THE HERBAL COMPOSITION HF2 AGAINST PYLORIC LIGATION INDUCED ULCER

Groups	Ulcer Index	Protection Index
Ligation Control	16.6	0.0
Ligation + HF2	1.65	84.08
Ligation + Omeprazole (10mg/Kg,p.o.)	6.6	51.44

INFERENCE: The composition of the present invention showed better protection than Omeprazole in the pyloric ligation induced ulcer model.

EXPERIMENT 6: EFFECT OF THE PRESENT COMPOSITION ON ACETYLCHOLINE AND HISTAMINE INDUCED CONTRACTION OF GUINEA-PIG ILEUM

METHOD: A piece of 2 - 3 cm of the terminal ileum of a freshly killed Guinea pig was suspended in an organ bath containing Tyrode solution at 34° C and bubbled with fresh air. Contraction was induced by submaximal contraction of acetylcholine chloride (1 [ig/mL) and Histamine (1 ng/mL) and it was recorded on a kymograph (According to the method of Patnaik 1992).

The composition HF2 (up to 250 ng / mL) did not exert any significant influence on isolated tissue preparation for anticholinergic (acetylcholine-induced contraction of Guinea-pig ileum) and Fk-anti-histaminic (Histamine induced contraction of Guinea-pig ileum) activity.

EXPERIMENT 7: HERBS AND PREPARATION OF THE COMPOSITION

For the purpose of conducting animal experiment all the herbs are washed dried and pulverised. All the herbs are taken in the proportion as shown in Table 6. The whole mixture is blended well and used for administering.

The components and their proportions of the standard herbal composition according to one embodiment of the present invention are listed in Table 6. The part of the herb which is used is also mentioned. The placebo preparation is designed to taste, smell and look like an Ayurvedic herbal composition.

TABLE 6: THE COMPOSITION OF THE HERBAL COMPOSITION HF2

S. No.	Name of the plant and its part used	Percentage
1.	<i>Aloe barbadensis</i> (elio)	6-12%
2.	<i>Asperagus racemosus</i> (Tubers)	5-13%
3.	<i>Glycyrrhiza glabra</i> (roots)	5-12%
4.	<i>Seaamum indicum</i> (seeds)	8-14%
5.	<i>Evolvulus aisinodes</i> (whole plant)	5-12%

6.	<i>Musa sapientum</i> (unripe fruit)	7-14%
7.	<i>Trachyparpum roxburghicinum</i> (fruits)	4-12%
8.	<i>Embelia ribes</i> (fruits)	9-14%
9	<i>Coriandrum sativum</i> (fruits)	7-14%
10.	<i>Cyclea peltate</i> (root)	6-13%
11	<i>Ferula asafoetida</i> (resin)	8-13%

TABLE 7: ANTIGASTRIC ULCER ACTIVITY OF THE HERBAL COMPOSITIONS HF3, HF4 AND HF5

Formulation	Cold restrained ulcer model	Pyloric ligation model	Alcohol induced ulcer model
HF3	66.69	41.75	86.54
HF4	45.86	17.0	79.42
HF5	45.86	62.75	85.75

In order to conduct a study on the synergistic effect, the herbal composition HF2 was taken and each component was removed and the effect of the resultant composition against cold restrained gastric ulcer model was studied. The results of the experiment thus conducted is tabulated in Table 8. It was concluded from the above experiments that the batch prepared by the removal of *Embelica ribes* has shown very good protection.

TABLE 8: RESULTS OF THE SYNERGISTIC EFFECT STUDY

S. No.	Details of Batch	Ulcer Index
1	HF2 without <i>Aloe barbadensis</i>	26.6
2	HF2 without <i>Asperagus racemosus</i>	11.6
3	HF2 without <i>Glycyrrhiza glabra</i>	15.0
4	HF2 without <i>Seamum indicum</i>	20.0
5	HF2 without <i>Evolvulus alisinoides</i>	13.3
6	HF2 without <i>Trachyspermum roxhurghianum</i>	20.0
7	HF2 without <i>Embelica ribes</i>	8.3
8	HF2 without <i>Coriandrum sativum</i>	10.0
9	HF2 without <i>Cyclea peltata</i>	11.66
10	HF2 without <i>Ferula asafetida</i>	13.0
11	HF2 without <i>Musa sapientum</i>	20.0

TABLE 9: COMPOSITION OF THE HERBAL COMPOSITIONS HF3, HF4 AND HF5

HF3	HF4	HF5
1. <i>Asperagus racemosus</i>	1. <i>Asperagus racemosus</i>	1. <i>Asperagus racemosus</i>
2. <i>Glycyrrhiza glabra</i>	2. <i>Glycyrrhiza glabra</i>	2. <i>Glycyrrhiza glabra</i>
3. <i>Seaamum indicum</i>	3. <i>Seaamum indicum</i>	3. <i>Seaamum indicum</i>
4. <i>Musa sapientum</i> and	4. <i>Musa sapientum</i>	4. <i>Musa sapientum</i>
5. <i>Trachyaparmum</i>	5. <i>Trachyaparmum</i>	5. <i>Trachyaparmum</i>
<i>roxburghicinum</i>	<i>roxburghicinum</i>	<i>roxburghicinum</i>
All in equal proportions	6. <i>Evolvulus aisinodes</i> and	6. <i>Evolvulus alsinodes</i>
	7. <i>Ferula asafoetida</i>	7. <i>Ferula asafoetida</i>
	All in equal proportions	8. <i>Coriandrum sativum</i>
		9. <i>Cyclea peltate</i> and
		10. <i>Aloe barbadensis</i>
		All in equal proportions

Claim:

1. A synergistic herbal composition for the treatment of gastric ulcer, said composition essentially comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and
5 *Trachyaparmum roxburghicinum* and optionally, powdered plant parts of *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum* *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes* along with one or more pharmaceutically acceptable additives/carriers.
2. A composition as claimed in claim 1, wherein the composition comprises powdered
10 plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyaparmum roxburghicinum* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
3. A composition as claimed in claim 1, wherein composition comprises powdered
15 plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Evolvulus aisinodes* and *Ferula asafoetida* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
4. A composition as claimed in claim 1, wherein the composition comprises powdered
20 plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Evolvulus alsinodes*, *Ferula asafoetida*, *Coriandrum sativum*, *Cyclea peltate* and *Aloe barbadensis* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
- 25 5. A composition as claimed in claim 1, wherein the composition comprises 5-13 wt. % of powdered plant parts of *Asperagus racemosus*, 5-12 wt. % of powdered plant parts of *Glycyrrhiza glabra*, 8-14 wt. % of powdered plant parts of *Seaamum indicum*, 7-14 wt. % of powdered plant parts of *Musa sapientum*, 4-12 wt. % of powdered plant parts of *Trachyaparmum roxburghicinum*, 6-12 wt. % of powdered plant parts of *Aloe barbadensis*, 5-12 wt. % of powdered plant parts of *Evolvulus aisinodes*, 6-13 wt. % of powdered plant parts of *Cyclea peltate* 9-14 wt. % of
30 powdered plant parts of *Embelia ribes*, 7-14 wt. % of powdered plant parts of *Coriandrum sativum* and 8-13 wt. % of plant parts of *Ferula asafoetida*, optionally along with one or more pharmaceutically acceptable additives/carriers.

6. A composition as claimed in claim 1, wherein the plant part of *Trachyparum roxburghicinum*, *Embelia ribes* and *Coriandrum sativum* is fruit.
7. A composition as claimed in claim 1, wherein the plant part of *Cyclea peltate* and
5 *Glycyrrhiza glabra* is root.
8. A composition as claimed in claim 1, wherein the plant part of *Aloe barbadensis* is elio.
9. A composition as claimed in claim 1, wherein the plant part of *Asperagus racemosus* is tuber.
- 10 10. A composition as claimed in claim 1, wherein the plant part of *Seaamum indicum* is seed.
11. A composition as claimed in claim 1, wherein the plant part of *Musa sapientum* is unripe fruit.
12. A composition as claimed in claim 1, wherein the plant part of *Ferula asafoetida* is
15 resin.
13. A synergistic herbal composition for the treatment of gastric ulcer, said composition comprising equal proportions of 10 powdered plant parts selected from the group comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or
20 more pharmaceutically acceptable additives/carriers.
14. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*,
25 *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida* and *Aloe barbadensis*, optionally along with one or more pharmaceutically acceptable additives/carriers.
15. A composition as claimed in claim 13, wherein said composition comprises equal
30 proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida* and *Evolvulus*

aisinodes, optionally along with one or more pharmaceutically acceptable additives/carriers.

16. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*,
5 *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
17. A composition as claimed in claim 13, wherein said composition comprises equal
10 proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
18. A composition as claimed in claim 13, wherein said composition comprises equal
15 proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable
20 additives/carriers.
19. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*,
25 *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
20. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*,
30 *Seaamum indicum*, *Musa sapientum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
21. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*,

Seaamum indicum, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.

- 5 22. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
- 10 23. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Asperagus racemosus*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
- 15 24. A composition as claimed in claim 13, wherein said composition comprises equal proportions of powdered plant parts of *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
- 20 25. A process for the preparation of the novel synergistic herbal composition for the treatment of gastric ulcer, said process comprising the steps of powdering plant parts essentially selected from *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum* and optionally, selected from *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*
- 25 *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, mixing the aforesaid powdered plant parts to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.
26. A process as claimed in claim 25, wherein said process comprises the steps of powdering plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum*
- 30 *indicum*, *Musa sapientum* and *Trachyparmum roxburghicinum*, mixing the aforesaid plant parts in equal proportions to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.

27. A process as claimed in claim 25, wherein said process comprises the steps of powdering plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Evolvulus aisinodes* and *Ferula asafoetida*, mixing the aforesaid plant parts in equal proportions to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.
28. A process as claimed in claim 25, wherein said process comprises steps of powdering plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Evolvulus alsinodes*, *Ferula asafoetida*, *Coriandrum sativum*, *Cyclea peltate* and *Aloe barbadensis*, mixing the aforesaid plant parts in equal proportions to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.
29. A process as claimed in claim 25, wherein said process comprises the steps of powdering and mixing 5-13 wt. % of plant parts of *Asperagus racemosus*, 5-12 wt. % of plant parts of *Glycyrrhiza glabra*, 8-14 wt. % of plant parts of *Seaamum indicum*, 7-14 wt. % of plant parts of *Musa sapientum*, 4-12 wt. % of plant parts of *Trachyaparmum roxburghicinum*, 6-12 wt. % of plant parts of *Aloe barbadensis*, 5-12 wt. % of plant parts of *Evolvulus aisinodes*, 6-13 wt. % of plant parts of *Cyclea peltate* 9-14 wt. % of plant parts of *Embelia ribes*, 7-14 wt. % of plant parts of *Coriandrum sativum* and 8-13 wt. % of plant parts of *Ferula asafoetida* to obtain a mixture and optionally adding one or more pharmaceutically acceptable additives/carriers to the above mixture.
30. A process as claimed in claim 25, wherein the plant part of *Trachyaparmum roxburghicinum*, *Embelia ribes* and *Coriandrum sativum* is fruit.
31. A process as claimed in claim 25, wherein the plant part of *Cyclea peltate* and *Glycyrrhiza glabra* is root.
32. A process as claimed in claim 25, wherein the plant part of *Aloe barbadensis* is elio.
33. A process as claimed in claim 25, wherein the plant part of *Asperagus racemosus* is tuber.

34. A process as claimed in claim 25, wherein the plant part of *Seaamum indicum* is seed.
35. A process as claimed in claim 25, wherein the plant part of *Musa sapientum* is unripe fruit.
36. A process as claimed in claim 25, wherein the plant part of *Ferula asafoetida* is resin.
37. A method of treating gastric ulcer in a subject, said method comprising administering an effective amount of the synergistic herbal composition essentially comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyaparmum roxburghicinum* and optionally, powdered plant parts of *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes* along with one or more pharmaceutically acceptable additives/carriers.
38. A method as claimed in claim 37, wherein said method comprises administering an effective amount of the synergistic herbal composition comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum* and *Trachyaparmum roxburghicinum* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
39. A method as claimed in claim 37, wherein said method comprises administering an effective amount of the synergistic herbal composition comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Evolvulus aisinodes* and *Ferula asafoetida* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
40. A method as claimed in claim 37, wherein said method comprises administering an effective amount of the synergistic herbal composition comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Evolvulus alsinodes*, *Ferula asafoetida*, *Coriandrum sativum*, *Cyclea peltate* and *Aloe barbadensis* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
41. A method as claimed in claim 37, wherein said method comprises administering an

- effective amount of the synergistic herbal composition comprising 5-13 wt. % of powdered plant parts of *Asperagus racemosus*, 5-12 wt. % of powdered plant parts of *Glycyrrhiza glabra*, 8-14 wt. % of powdered plant parts of *Seaamum indicum*, 7-14 wt. % of powdered plant parts of *Musa sapientum*, 4-12 wt. % of powdered plant parts of *Trachyaparmum roxburghicinum*, 6-12 wt. % of powdered plant parts of *Aloe barbadensis*, 5-12 wt. % of powdered plant parts of *Evolvulus aisinodes*, 6-13 wt. % of powdered plant parts of *Cyclea peltate* 9-14 wt. % of powdered plant parts of *Embelia ribes*, 7-14 wt. % of powdered plant parts of *Coriandrum sativum* and 8-13 wt. % of plant parts of *Ferula asafoetida* in equal proportions, optionally along with one or more pharmaceutically acceptable additives/carriers.
42. A method as claimed in any one of the claims 37 to 41, wherein the subject is a mammal including human.
43. A method as claimed in any one of the claims 37 to 41, wherein the effective dosage of the composition per day is in the range of 5 to 15g.
44. A method as claimed in any one of the claims 37 to 41, wherein the composition can be in the form of tablets, capsules, syrup and any other conventional forms.
45. A method as claimed in any one of the claims 37 to 41, wherein the composition is administered orally, intra-muscularly, and by any other conventional methods.
46. A method as claimed in any one of the claims 37 to 41, wherein the composition may be used for therapeutic as well as prophylactic treatment of gastric ulcer.
47. A method as claimed in any one of the claims 37 to 41, wherein the subject may be administered a bolus dose or a multiple dose.
48. A method of treating gastric ulcer in a subject, said method comprising administering an effective amount of the synergistic herbal composition comprising equal proportions of 10 powdered plant parts selected from the group comprising of powdered plant parts of *Asperagus racemosus*, *Glycyrrhiza glabra*, *Seaamum indicum*, *Musa sapientum*, *Trachyaparmum roxburghicinum*, *Cyclea peltate*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafoetida*, *Aloe barbadensis* and *Evolvulus aisinodes*, optionally along with one or more pharmaceutically acceptable additives/carriers.
49. A method as claimed in claim 41, wherein the composition showed more than 62% protection against cold restraint ulcer model.

50. A method as claimed in claim 41, wherein the composition showed more than 30 % protection against aspirin induced ulcer model.
51. A method as claimed in claim 41, wherein the composition reduced the length of
5 hemorrhagic bands to 22.67 ± 4.69 (mm \pm SE) against alcohol induced gastric ulcer.
52. A method as claimed in claim 41, wherein the composition has protection index greater than 80 against pyloric ligation induced ulcer.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 03/04807

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K35/78

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)

IPC 7 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 practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE, SCISEARCH, PASCAL, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	MITRA S K ET AL: "PROTECTIVE EFFECT OF UL-409, A HERBAL FORMULATION AGAINST PHYSICAL AND CHEMICAL FACTOR INDUCED GASTRIC AND DUODENAL ULCERS IN EXPERIMENTAL ANIMALS" JOURNAL OF ETHNOPHARMACOLOGY, ELSEVIER SCIENTIFIC PUBLISHERS LTD, IE, vol. 52, no. 3, 1996, pages 165-169, XP001119018 ISSN: 0378-8741 abstract -----	

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in 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 document 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.

Z document member of the same patent family

Date of the actual completion of the international search

14 June 2004

Date of mailing of the International search report

23/06/2004

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 03/04807

Box I Observations where certain claims were found unsearchable (Continuation of item 1 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:

Although claims 37-52 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
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:

see FURTHER INFORMATION sheet PCT/ISA/210
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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

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 fee, this Authority did not invite payment of any additional fee.
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.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 37-52 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box I.2

Claims Nos.: -

Present claims 1-52 relate to a composition/method defined by reference to the following wrong scientific plant names: Asperagus, Seaamum and Trachyaparmum roxburghicinum.

This is considered to lead to a lack of clarity within the meaning of Article 6 PCT. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to a composition comprising at least 4 of the 5 species Asparagus racemosus, Glycyrrhiza glabra, Sesamum indicum, Musa sapientum and Trachyspermum roxburghianum.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.