

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 May 2007 (24.05.2007)

PCT

(10) International Publication Number
WO 2007/057924 A1

(51) International Patent Classification:
A61K 36/68 (2006.01) A61K 47/36 (2006.01)

(21) International Application Number:
PCT/IN2006/000462

(22) International Filing Date:
20 November 2006 (20.11.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
3100/DEL/2005 21 November 2005 (21.11.2005) IN
3353/DEL/2005 13 December 2005 (13.12.2005) IN

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN,
CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,
GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS,
JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS,
LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY,
MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS,
RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (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))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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.

(54) Title: LAXATIVE COMPOSITION ON THE BASIS OF TRIPHALA

(57) Abstract: Laxative composition comprising ispaghula, a saccharide component and optionally triphala mixed with optionally one or more excipient(s). Also provided are a process and a method of using such compositions. The compositions of the present invention are useful as pharmaceuticals or dietary supplements and are highly effective in the overall management of constipation and associated disorders thus providing a better relief to the user.



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NOVEL COMPOSITIONS FOR MANAGEMENT OF CONSTIPATION

FIELD OF THE INVENTION

The present invention relates to novel compositions comprising at least one bowel
5 evacuant and a saccharide component optionally with at least one component selected
from a group comprising antacid, antiflatulant, prokinetic, antispasmodic,
anticholinergic, stool softener, anti-nauseating/anti-emetic agent, tonifier and the like or
their mixtures, and optionally with one or more excipient(s); the process of preparation
and method of using such compositions. The compositions of the present invention are
10 useful as a pharmaceutical or a dietary supplement. The compositions of the present
invention are highly effective in the overall management of constipation including the
prophylaxis and/or amelioration and/or treatment of not only the constipation but also
associated disorders thus providing a better relief to the user.

15 BACKGROUND OF THE INVENTION

Constipation is a condition in which a person has uncomfortable or infrequent bowel
movements. Generally, a person is considered to be constipated when bowel
movements result in passage of small amounts of hard, dry stool, usually fewer than
three times a week. People who are constipated may find it difficult and painful to have
20 a bowel movement. Other symptoms of constipation include feeling bloated,
uncomfortable, and sluggish. The hard and dry stools of constipation occur when the
colon absorbs too much water or if the colon's muscle contractions are slow or
sluggish, causing the stool to move through the colon too slowly. Common causes of
constipation are not enough fiber in the diet, not enough liquids, lack of exercise,
25 medications, irritable bowel syndrome, changes in life or routine such as pregnancy or
older age or travel, abuse of laxatives, ignoring the urge to have a bowel movement,
specific diseases such as stroke, problems with the colon and rectum and problems with
intestinal function such as chronic idiopathic constipation. Sometimes constipation can
lead to complications such as hemorrhoids caused by straining to have a bowel
30 movement or anal fissures caused when hard stool stretches the sphincter muscle or
rectal prolapse caused by straining which leads to a small amount of intestinal lining to
push out from the anal opening. Constipation may also cause hard stool to pack the

intestine and rectum so tightly that normal pushing action of colon is not enough to expel stool. This condition, called fecal impaction, occurs mostly in children and older adults.

5 US patent no. 5,320,847 relates to a method of agglomerating, and thereby increasing the dispersability and mixability of, a powdered psyllium hydrophilic mucilloid combine utilizing acacia dissolved in water as the agglomerating agent. US patent no. 5,651,988 claims a combination osmotic and bulk-forming laxative comprising lactitol and psyllium hydrophilic mucilloid powder. US patent no. 4,321,263 describes a
10 method of increasing the water dispersability of psyllium hydrophilic mucilloid by granulating or agglomerating the psyllium with an alcoholic solution of polyethylene glycol and/or polyvinylpyrrolidone. Yet another method is disclosed in US patent no. 4,548,806 which describes a method for coating psyllium hydrophilic mucilloid with from about 3-11 percent by weight of a water soluble maltodextrin.

15

US publication no. 20050152989 claims a method for treating irritable bowel syndrome (IBS), using an osmotic laxative and a fiber which specifically provides relief from IBS by simultaneously ameliorating both constipation and diarrhea. Particularly described fibers are psyllium, partially-hydrolyzed guar gum and cellulose. PCT publication no.
20 WO2005051361 relates to solid dosage form colonic purgative formulations particularly comprising at least one soluble binder and at least one purgative and methods of their use.

PCT publication bearing no. WO2004078182 relates to a novel composition which
25 combines defined proportions of a soluble saccharide which is poorly absorbed by the organism (the most widely known being disaccharides such as lactulose, lactitol, trehalose) and an antifatulent from the siloxane group (the most widely known being polydimethylsiloxanes such as simethicone, dimethicone). German patent publication bearing no. 10262005 claims compositions containing hydrogenated condensed
30 palatinose together with bifidobacteria cultures or with at least one other dietary fiber component selected from long- or short-chain fructo-oligosaccharides, galacto-, xylo-, malto-, isomalto-, gentio-, soybean-, chito- or chitosan-oligosaccharides, hydrolyzed guar gum, lactulose, lacto-sucrose, pectic materials, hydrolases, sugar condensation

products, glucosyl-sucrose, resistant starch, cellulose or oat-, wheat-, vegetable-, fruit- or sugar beet fiber. European patent no. 0334407 relates to a method of preparing a solid composition of lactulose in a simple way. According to the European patent no. 0334407, the lactulose syrup is mixed with Fiberform™ i.e. a fiber product based on
5 the husks of corn grains having a fiber content of more than 80%. The mixture is spread, dried, crushed and optionally sieved. US patent no. 5,817,330 describes jellied and translucent emulsion, characterized in that it consists essentially of about 75 to 85 parts by weight of liquid paraffin oil and 25 to 15 parts by weight of a sweetened aqueous solution of lactulose containing a total of 54 to 66% by weight dry matter.

10

Laxatives are among the most commonly used drugs or additives for treatment of constipation. Most are quite safe when used judiciously, intermittently when possible, and in the absence of contraindications. Bulking agents and nonabsorbable compounds such as lactulose can cause bloating. Osmotic laxatives containing poorly absorbable
15 ions such as magnesium or phosphate can cause metabolic disturbances, particularly in the presence of renal impairment. Polyethylene glycol solutions are emerging as an effective and safe mode of treatment for chronic constipation. Purgatives are drastic laxatives causing a cleansing or watery evacuation of the bowels, usually with a griping pain.

20

Triphala is an ayurvedic herbal formula composed of three fruits namely Harada (*Haritaki*), Amla (*Amalaki*) and Behada (*Bibhitaki*), and is an effective laxative which also supports the body's strength. The major components of Triphala are condensed tannins, catechins, along with gallic and ellagic acid which are the building blocks of
25 the tannins. Because of its high nutritional value, Triphala uniquely cleanses and detoxifies at the deepest organic levels without depleting the body's reserves. Triphala corrects constipation, cleanses and tonify the gastrointestinal tract; detoxifies the whole body and improves digestion and assimilation; reduces high blood pressure and hypertension and improves blood circulation; acts as anti-viral, anti-bacterial, powerful
30 anti-oxidant; and has anticancer and anti-allergy properties. Triphala is also helpful in liver disorders, acts as an expectorant and corrects diverticulitis. It is very effective in Irritable Bowel Syndrome (IBS) and Ulcerative Colitis. Triphala is a powerful eye rejuvenator for treatment of conjunctivitis, progressive myopia, the early stages of

glaucoma and cataracts. It is highly anti-inflammatory, anti-viral and also stimulates bile-flow and peristalsis. Triphala is mild, non-habit forming, and a rejuvenative. Triphala (trifala) is so effective because its three herbs are potent healers. The herb Amalaki (*Emblica officinalis* or *Phyllanthus emblica*) is one of ayurveda's
5 greatest rejuvenators and a strong natural anti-oxidant, which also helps to boost the immune system and balances 'Pitta'. The herb Haritaki (*Terminalia chebula*) the Tibetan "king of medicine" is a classic heart-brain-longevity tonic and balances 'Vata'. The herb Bibhitaki (*Terminalia belerica*) is a powerful rejuvenative that reduces liver and heart disease; improves the voice, vision and promotes the growth of hair and
10 balances 'Kapha'. Triphala helps to feel pure, light and revitalized; removes toxins, accumulations, gas and distention; nourishes the nervous system, blood and muscle; increases digestion, assimilation and reduces fat; detoxifies almost every system in the body and regulates the metabolism. Recent studies have shown that triphala extract possess the ability to scavenge free radicals such as DPPH and superoxide primarily
15 due to the presence of phenolic compounds. Studies have also shown the strong inhibitory activity of triphala on PMN-type MMPs involved in the extracellular matrix (ECM) degradation during periodontitis. The *in vitro* cytotoxic and apoptotic activity of Triphala had also been demonstrated, which may be due to the gallic acid - a major polyphenol observed in Triphala. However, no medicinal compositions had been
20 described in prior art comprising Triphala and an osmotic laxative for treatment of constipation and associated disorders.

Ajwain oil is an essential oil obtained from the dried fruits of *Trachyspermum ammi*. The essential oil (2.5 to 5% in the dried fruits) is dominated by thymol (35 to 60%);
25 furthermore, α -pinene, *p*-cymene, limonene and γ -terpinene have been found. The oil of ajwain is an almost colorless to brownish liquid with characteristic odour and a sharp hot taste. Ajwain oil is highly effective as a remedy for gastrointestinal disorders such as for relieving flatulence, dyspepsia, colic, diarrhea, spasmodic disorders and indigestion.

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Fibers are often used for the treatment of constipation. A fiber is the non-digested part of plant food and adds bulk to the stools by absorbing water. There are two types of fiber namely soluble and insoluble. Soluble fiber dissolves in water and is found in oat

bran, barley, peas, beans, and citrus fruits. Insoluble fibers are found in wheat bran and some vegetables. Fiber increases the transit time of the colon and decrease the pressures within the colon. Fibers such as Psyllium have been reported to inhibit lactulose-induced colonic mass movements and to benefit patients with irritable bowel syndrome, improving both constipation and diarrhea (Washington N et al, The American journal of clinical nutrition, 1998, 67(2), 317-321). Psyllium is the common name used for several members of the plant genus *Plantago* whose seeds are used commercially for the production of mucilage. The genus *Plantago* contains over 200 species. *P. ovata* and *P. psyllium* are produced commercially in several European countries, the former Soviet Union, Pakistan, and India. *Plantago* seed known commercially as black, French or Spanish psyllium is obtained from *P. psyllium* and *P. arenaria*. Seed produced from *P. ovata* is known in trading circles as white or blonde psyllium, Indian Plantago or Ispaghula or Isabgol. Senna is the common name for many species in the genus *Cassia*, both in the subfamily Caesalpinioideae. The term "Senna" is often used specifically for the medicinal herb *Cassia angustifolia*. Senna contains hydroxyanthracene glycosides known as sennosides. These glycosides stimulate colon activity and thus have a laxative effect. Also, these glycosides increase fluid secretion from the colon, with the effect of softening the stool and increasing its bulk (Leng-Peschlow E. Dual; effect of orally administered sennosides on large intestinal transit and fluid absorption in the rat. *J Pharm Pharmacol* 1986; 38:606-10). Double-blind trials have confirmed the benefit of senna in treating constipation (Passmore AP, Davies KW, Flanagan PG, et al; A comparison of Agiolax and Lactulose in elderly patients with chronic constipation. *Pharmacol* 1993;47(suppl 1):249-52 & Kinnunen O, Winblad I, Koistinen P, Salokannel J; Safety and efficacy of a bulk laxative containing senna versus lactulose in the treatment of chronic constipation in geriatric patients. *Pharmacol* 1993; 47(suppl 1):253-5). Constipation induced by drugs such as the anti-diarrheal medicine loperamide (Imodium®) has also been shown to be improved by senna in a clinical trial (Ewe K, Ueberschaer B, Press AG; Influence of senna, fibre, and fibre & senna on colonic transit in loperamide-induced constipation. *Pharmacol* 1993; 47(suppl 1):242-8).

Constipation is often associated with several disorders such as gas, bloating, cramps, acidity, nausea, irritation, abdominal discomfort and pain. Although several prior art

literature is available for the treatment of constipation but still there exists an unmet need for compositions which would be effective in the overall management of constipation including the prophylaxis or amelioration or treatment of not only the constipation but also associated disorders thus providing a better relief to the user. The novel compositions of the present invention overcomes such limitations of prior art.

SUMMARY OF THE INVENTION

It is an objective of the present invention to provide novel compositions comprising at least one bowel evacuant as the active agent and a saccharide component, optionally with at least one component selected from a group comprising antacid, stool softener, antifatulent, prokinetic, anti-emetic and tonifier, and optionally one or more excipient(s).

It is an objective of the present invention to provide novel compositions comprising at least one laxative and/or a purgative as the bowel evacuant and a saccharide component, optionally with at least one component selected from a group comprising antacid, stool softener, antifatulent, prokinetic, anti-emetic and tonifier, and optionally one or more excipient(s).

It is an objective of the present invention to provide novel compositions comprising at least one laxative and/or a purgative as the bowel evacuant, a saccharide component and at least one tonifier, optionally with at least one component selected from a group comprising antacid, stool softener, antifatulent, prokinetic and anti-emetic, and optionally one or more excipient(s).

It is an objective of the present invention to provide novel compositions comprising ispaghula as the bowel evacuant and lactulose as the saccharide component, triphala as the tonifier, optionally with at least one component selected from a group comprising docusate sodium as the stool softener, simethicone as the antifatulent, antacid and prokinetic, and one or more excipients.

It is an objective of the present invention to provide novel compositions comprising ispaghula and triphala as bowel evacuants and lactulose as the saccharide component,

optionally with at least one component selected from a group comprising docusate sodium as the stool softener, simethicone as the antiflatulant, antacid and prokinetic, and one or more excipients.

5 It is an objective of the present invention to provide novel compositions comprising triphala as the as the bowel evacuant and lactulose as the saccharide component, optionally with at least one component selected from a group comprising peppermint, fennel, ajwain, mentha extract and lactobacillus optionally with at least one antacid and/or an antiflatulant and/or a prokinetic, and one or more excipients.

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It is another objective of the present invention to provide process for preparation of such compositions.

15 It is yet another objective of the present invention to provide method of using such compositions which comprises administering to a subject in need thereof an effective amount of the composition.

20 The novel compositions of the present invention can be manufactured for pharmaceutical use or can be used as a dietary supplement and are useful in the overall management of constipation including the prophylaxis and/or amelioration and/or treatment particularly of constipation and associated disorders.

DETAILED DESCRIPTION OF THE INVENTION

25 The present invention provides novel composition comprising at least one bowel evacuant as the active agent and a saccharide component, optionally with at least one component selected from a group comprising antacid, stool softener, antiflatulant, prokinetic, anti-emetic and tonifier, and optionally one or more excipient(s).

30 In an embodiment of the present invention is provided novel compositions comprising at least one laxative and/or a purgative as the bowel evacuant and a saccharide component, optionally with at least one component selected from a group comprising antacid, stool softener, antiflatulant and prokinetic agent, and one or more excipients.

In an embodiment of the present invention is provided novel compositions comprising at least one laxative and/or a purgative as the bowel evacuant, a saccharide component and at least one tonifier, optionally with at least one component selected from a group comprising antacid, stool softener, antiflatulant and prokinetic, and one or more
5 excipients.

Preferably the bowel evacuant is a laxative such as triphala or ispaghula or a purgative such as senna; the saccharide component is lactulose, the stool softener is docusate sodium, the antiflatulant is simethicone; the prokinetic/anti-nauseating/anti-emetic
10 agent is domperidone or tegaserod.

In an embodiment of the present invention is provided a novel composition comprising ispaghula as the bowel evacuant, lactulose as the saccharide component, triphala as the tonifier and optionally with at least one component selected from a group comprising
15 docusate sodium as the stool softener and/or simethicone as the antiflatulant optionally with at least one antacid and/or a prokinetic, and one or more excipients.

In an embodiment of the present invention is provided a novel composition comprising ispaghula and triphala as bowel evacuants and lactulose as the saccharide component,
20 optionally docusate sodium as the stool softener and/or simethicone as the antiflatulant optionally with at least one antacid and/or a prokinetic, and one or more excipients. In a preferred embodiment, the composition of the present invention comprises ispaghula as the bowel evacuant, lactulose as the saccharide component, and triphala as the tonifier, optionally with one or more excipients.

25 In another embodiment, the composition of the present invention comprises triphala as the as the bowel evacuant and lactulose as the saccharide component, optionally with at least one component selected from a group comprising peppermint, fennel, ajwain, mentha extract and lactobacillus optionally with at least one antacid and/or an
30 antiflatulant and/or a prokinetic, and one or more excipients.

In an embodiment of the present invention, the bowel evacuant is selected from but not limited to a group comprising triphala; bulk laxatives such as ispaghula powder,

methylcellulose (Citrucel), polycarbophil, malt soup extract, ethulose, sterculia, linseed, triticum or mixtures thereof; osmotic laxatives such as magnesium carbonate, magnesium oxide, magnesium peroxide, magnesium sulfate, mineral salts in combination, sodium sulfate, pentaerithryl, macrogol, glycerol, sodium phosphate, 5 magnesium citrate, sodium tartrate, or mixtures thereof; stool softeners such as docusate, poloxamer 188, dioctyl sodium sulfosuccinate, or mixtures thereof; lubricant/emollient such as mineral oil; hydrating agents such as dibasic sodium phosphate, magnesium citrate, magnesium hydroxide (Milk of Magnesia), magnesium sulphate, monobasic sodium phosphate, sodium biphosphate, or mixtures thereof; 10 carbon dioxide releasing laxatives such as potassium bitartrate, sodium bicarbonate, or mixtures thereof; and the like used either alone or in combination thereof.

In a preferred embodiment, the bowel evacuant of the present invention is Ispaghula or Triphala either used as an extract or in the powder form. The extract can be aqueous or 15 non-aqueous. The solvents used in the non-aqueous extraction process is selected from but not limited to a group comprising alcohols such as methanol, ethanol, butanol, isopropyl alcohol or the like; acetone; glycerol; ethylacetate and alkylene glycols such as methylene glycol, ethylene glycol, propylene glycol or the like used either alone or in combination thereof. A hydro-alcoholic extract is preferred. The general procedure 20 for the preparation of the Triphala extract is as follows: Equal parts of dried Amalaki (*Embllica officinalis* or *Phyllanthus emblica*), Haritaki (*Terminalia chebula*) and Bibhitaki (*Terminalia belerica*) are taken and mixed together followed by pulverization. The powder thus obtained (hereinafter referred to as 'Triphala powder') is then extracted with a suitable solvent (aqueous, non-aqueous or hydro-alcoholic) 25 preferably by applying heat. The extraction is preferably done 3-5 times under heat and reflux conditions to ensure proper extraction. Then the solvent is removed from the liquid extract to obtain the dry extract. The dry extract (referred to hereinafter as 'Triphala extract') thus obtained is preferably sifted through a suitable sieve to break any lumps or agglomerates. The general procedure for the preparation of the psyllium 30 seed husks extract is as follows: Milled psyllium seed husks were stirred with potassium hydroxide containing sodium borohydride in a nitrogen atmosphere. The mixture was centrifuged. The supernatant was decanted from an insoluble fraction that had settled out in the centrifuge bottle. The insoluble fraction was stirred with fresh

potassium hydroxide-sodium borohydride solution and re-centrifuged. The supernatants from both centrifugations were combined. The pH of the combined supernatants was adjusted to 4.5 with glacial acetic acid, with stirring, at ambient temperature, then again centrifuged. The supernatant was decanted from a gel mass that had settled out in the
5 centrifuge bottle. The gel was washed gently with water to remove adhering supernatant solution and this wash water was added to the supernatant. The gel fraction was desiccated by treatment with 95% ethanol and finally washed with diethyl ether and dried. Prior to desiccating, in some instances the fraction was further purified by repeating the alkaline solubilization and acidification steps described above. The gel
10 was re-suspended in potassium hydroxide, acidified to pH 4.5 and centrifuged to recover the gel.

In another embodiment of the present invention, the tonifier used in the composition is triphala. In further embodiment of the present invention, the bowel evacuant comprises
15 a mixture of Triphala and Ispaghula. In the present invention, the Triphala particularly acts as a tonifier and detoxifier especially for the gastro-intestinal tract (GIT). Such compositions are employed for prophylaxis, amelioration or therapeutic treatment of constipation and other associated disorders and also serve as an effective remedy particularly for extended periods of time thus leading to considerable patient
20 compliance.

In another embodiment, the saccharide component is selected from but not limited to a group comprising lactulose, lactitol, sorbitol, mannitol, maltodextrin, dextran, sucrose, maltitol, dextrose and the like or mixtures thereof.

25 The purgatives useful in the present invention include but not limited to a group comprising casanthranol, cascara, aloe, castor oil, dehydrocholate, phenolphthalein, senna, sennosides, sodium picosulfate, dantron, bisoxatin or the like used either alone or in combination thereof. The dried ripe fruits, pods or leaves of Senna (preferably
30 *Cassia angustifolia*) as powder, concentrated infusion or liquid extract can be used in the present invention.

Particularly preferred bulk laxatives for use in the present invention are fibers. Two

types of fibers namely soluble and insoluble can be used in the composition of the present invention. Soluble fibers are viscous, gel-forming fibers which absorb water and makes stools softer and easier to pass. Further, soluble fibers are the edible parts of plants or similar carbohydrates resistant to digestion and absorption in the human small intestine with complete or partial fermentation in the large intestine. Fermentation of the undigested soluble fibers occurs by the action of colonic bacteria, producing gases and short-chain fatty acids such as butyric, acetic, propionic, and valeric acids. Soluble fibers found in psyllium seed husk (about 66% soluble fibers); vegetable gums from legumes (guar gum, locust bean gum) and gummy exudates (gum acacia and tragacanth); seed mucilages from oats, rye and barley; mucilages from certain vegetables and roots such as broccoli, carrots, lady fingers, yam; pectin from fruits and vegetables are particularly used. Insoluble fibers are indigestible cellulosed and lignified vegetable fibers found in cereal brans and fruit skins, which absorb water but do not dissolve in it. The insoluble fibers are also not fermented in the intestine. Insoluble fibers useful in the present invention are found in fruits, vegetables, whole grain breads, and cereals. Wheat bran contains mostly insoluble fiber, while oat bran contains about 7% soluble fiber. Synthetic fibers may also be useful in the present invention. Several synthetic water soluble or water absorbing fibers have been prepared by modification of cellulose and other natural fibers such as methyl cellulose, carboxymethyl cellulose, polycarbophil and the like.

The novel composition of the present invention can be manufactured for pharmaceutical use or can be used as a dietary supplement. The composition of the present invention particularly upon daily use help in restoring normal bowel functions, and also tonifies and detoxifies the GIT.

In a further embodiment of the present invention, a blend of *Lactobacillus* cultures and/or other useful microorganisms with or without an amino acid such as L-lysine which colonize the intestine can also be used as an additional component. These cultures continually produce enzymes which support the digestive system and normalize the intestine, which aids normal digestion. It also provides relief for cramps, bloating, diarrhea, constipation and urgency. Such probiotics are preferably selected from but not limited to different *Lactobacillus species* used either alone or in

combination such as *Lactobacillus reuteri* and *Lactobacillus paracasei*.

Antacids useful in the present invention are selected from but not limited to a group comprising alkaline earth metal oxides, peroxides, hydroxides, and the like or mixtures thereof. Anti-gas/antiflatulant agents useful in the present invention is selected from but not limited to a group comprising simethicone, dimethicone, bisacodyl, alpha-galactosidase enzyme, activated charcoal and the like or mixtures thereof. These agents particularly aid in the reduction of acid and gas/flatulence and the accompanying lower abdominal pain.

Prokinetic agents useful in the compositions of the present invention primarily to improve the motility of the gastrointestinal tract are selected from but not limited to a group comprising 5HT4 agonist and 5HT3 antagonist such as cisapride, itopride, mosapride, domperidone, metoclopramide, tegaserod and the like or mixtures thereof. Natural prokinetics such as Dai-kenchu-to can also be used. Smooth muscle relaxants such as mebeverine, peppermint oil and ajwain oil that have direct relaxant properties on gut smooth muscle are also useful. Antispasmodic agents such as dicyclomine and hyoscyamine are also useful. Anticholinergic agents that can be used in the present compositions as additional components act by decreasing the abnormal sensitivity of cholinergic (muscarinic M2) receptors in gut smooth muscle leading to significant improvement in abdominal pain and rectal urgency. Other categories of active agents suitable for the treatment of disorders associated with constipation can also be used in the composition of the present invention. The stool softener useful in the compositions of the present invention is selected from but not limited to a group comprising docusate sodium, soluble fibers and the like or mixtures thereof. Such agents are employed to keep stool soft for easy natural passage and avoid painful anorectal conditions.

Additionally other ingredients such as carminatives, ginger, turmeric, chamomile, caraway, fennel, mentha extract, or any other natural or semi-synthetic or synthetic ingredient useful for the management of constipation or associated disorders can be used in the present invention to relax and calm the stomach and promote healthy digestion, preferably incorporated into the composition as oils. The novel compositions of the present invention also assist in relief and discomfort of gas, acid indigestion, sour stomach, upset stomach or cramps associated with constipation. Various enzymes either

alone or in combination that can be used in the present invention include but not limited to lactase that helps in digesting the lactose, or milk sugar, found in dairy products; alpha-galactosidase that helps in digesting the complex sugars found in beans and other legumes and in cruciferous vegetables; protease that helps to break down the peptide
5 bonds in protein foods; amylase that helps to digest the starchy carbohydrates in foods and lipase which helps to digest the fats in food. Sweeteners such as aspartame, acesulfame, saccharine, cyclamate, glycyrrhizin, steviosides, talin, dihydrochalcone compounds and mixtures thereof can also be used in the present invention, preferably in a quantity from about 0.001% to about 3% by weight of the composition.

10 The one or more excipient(s) that can be used for preparation of such compositions are selected from but not limited to diluents, disintegrants, binders, fillers, bulking agents, anti-adherants, anti-oxidants, buffering agents, colorants, flavoring agents, coating agents, plasticizers, organic solvents, stabilizers, preservatives, lubricants, glidants,
15 chelating agents, release modifiers and the like known to the art used either alone or in combination thereof. In an embodiment, the fillers used in the present invention is selected from but not limited to a group comprising lactose, mannitol, sorbitol, starch, microcrystalline cellulose, xylitol, fructose, sucrose, dextrose, dicalcium phosphate, calcium sulphate, maltodextrin; polyethylene glycol such as PEG 100, PEG 2000, and
20 PEG 6000; polyvinylpyrrolidone; sodium chloride; sodium citrate; citric acid; water soluble celluloses such as low viscosity hydroxyethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose and the like or mixtures thereof. The disintegrants used in the present invention include but not limited to starch or its derivatives, pregelatinized starch, croscarmellose sodium, sodium starch glycollate, and
25 the like used either alone or in combination thereof. The lubricants used in the present invention include but not limited to talc, magnesium stearate, calcium stearate, stearic acid, hydrogenated vegetable oil and the like used either alone or in combination thereof. The release modifiers used in the present invention is selected from but not limited to a group comprising methacrylic acid copolymers such as Eudragit®,
30 cellulosic polymer such as alkyl celluloses or hydroxyalkyl celluloses, gums, hydrophilic polysaccharides such as alginates, chitosan, scleroglucan or semi-synthetic polysaccharides; lipid components such as hydrogenated vegetable oils, waxes, glyceryl behenate and the like, or mixtures thereof.

In an embodiment, the compositions of the present invention are in the form of immediate release or controlled release or a combination of immediate release and controlled release particularly intended for delivery of the active agent(s) for an extended time period. The dosage form may be in the form of tablets, minitables, capsules, pellets, granules, patches, powders, sachets or liquids or other dosage forms suitable for preferably oral administration, or enemas or suppositories. In a preferred embodiment, the composition of the present invention is in the form of granules, or powder filled into sachets or capsules, or granules or powder compressed into tablets that may be optionally filled into capsules.

10

In another embodiment, the composition of the present invention is highly effective in the management of constipation including prophylaxis and/or amelioration and/or treatment of constipation and associated disorders such as gas, bloating, cramps, acidity, irritation, abdominal pain and discomfort thus providing a better relief to the user. In a still further embodiment, the composition of the present invention is useful in the treatment and/or management of diseases or disorders of the bowel primarily associated with constipation, diarrhea or indigestion.

The present invention also provides process for preparation of such compositions. In an embodiment, the process for preparation comprises mixing the active agent(s) and saccharide component optionally with at least one component selected from a group comprising antacid, stool softener, antifatulant, prokinetic, anti-emetic and tonifier, and one or more excipient(s) and formulating into a suitable dosage form.

In yet another embodiment of the present invention is provided method of using such composition which comprises administering to a subject in need thereof an effective amount of the composition. In a further embodiment is provided a method, wherein the composition of the present invention is useful for prophylaxis and/or amelioration and/or treatment of constipation and associated disorders such as gas, bloating, cramps, acidity, irritation, abdominal pain and discomfort. In a still further embodiment is provided a method, wherein the composition of the present invention is useful as a dietary supplement to normalize bowel functions and provide relief from particularly constipation and other associated disorders.

In yet another embodiment is provided method of using such composition as a dietary supplement to normalize bowel functions and provide relief from particularly constipation or other associated disorders. The compositions of the present invention are also useful in the treatment and/or management of diseases or disorders of the bowel primarily associated with constipation, diarrhea or indigestion. The compositions of the present invention are also useful for the treatment/management of Irritable Bowel Syndrome (IBS) predominantly associated with constipation.

The examples given below serve to illustrate embodiments of the present invention. However they do not intend to limit the scope of the present invention in any manner whatsoever.

EXAMPLES

Example-1

S. No.	Ingredient	Quantity (per serving)
1.	Ispaghula husk powder	3.50 g
2.	Lactulose powder	10.00 g
3.	Triphala powder	1.00 g
4.	Methyl paraben sodium	30.00 mg
5.	Propyl paraben sodium	3.00 mg
6.	Sodium saccharin	20.00 mg
7.	Purified water	q.s. (lost in processing)

Procedure:

- i) Ispaghula husk powder, Lactulose powder and Triphala powder were sifted through # 40 mesh sieve and mixed well.
- ii) Methyl paraben sodium, Propyl paraben sodium and Sodium saccharin were dissolved in Purified water.
- iii) The material of step (i) was granulated with the solution of step (ii).
- iv) Granules of step (iii) were dried and sifted through # 30 mesh sieve and delivered in the form of sachets.

Example-2

S. No.	Ingredient	Quantity (mg/tablet)
1.	Triphala extract	325.0

2.	Lactulose	1000.0
3.	Polyvinylpyrrolidone	50.0
4.	Dried Starch powder	50.0
5.	Magnesium stearate	10.0

5 **Procedure:**

- i) Triphala extract and Lactulose were sifted through # 30 mesh sieve and mixed.
- ii) Polyvinylpyrrolidone and Dried Starch powder were sifted through #40 mesh sieve.
- iii) The material of step (i) was mixed the material of step (ii).
- 10 iv) Magnesium stearate was sifted through #60 mesh sieve and added to the material of step (iii) followed by mixing.
- v) The material of step (iv) was compressed into tablets.

Example-3

15	S. No. Ingredient	Quantity (per serving)
	1. Triphala extract	325.0 mg
	2. Lactitol	10.0 g
	3. Ajwain oil	50.0 mg
	4. Purified water	q.s. (lost in processing)
20	5. Sodium saccharin	0.01 g

Procedure:

- i) Triphala extract and Lactitol were sifted through # 30 mesh sieve and mixed.
- ii) Ajwain oil was added to the material of step (i) and mixed.
- iii) Sodium saccharin was dissolved in Purified water.
- 25 iv) The material of step (ii) was granulated using the material of step (iii) to obtain the granules which were then dried.
- v) The material of step (iv) was passed through #30 mesh sieve to yield the product.

30 **Example-4**

S. No. Ingredient	Quantity (per serving)
1. Triphala extract	0.65 g
2. Maltitol	10.00 g

3.	Alpha-galactosidase enzyme	380 GalU
4.	Purified water	q.s. (lost in processing)
5.	Sodium saccharin	0.01 g

Procedure:

- 5 i) Triphala extract, Alpha-galactosidase enzyme and a part of Maltitol were mixed.
- ii) Remaining part of Maltitol and Sodium saccharin were dissolved in Purified water.
- 10 iii) The material of step (i) was granulated using the material of step (ii) to obtain the granules which were then dried.
- iv) The material of step (iii) was passed through #30 mesh sieve to yield the product.

Example-5

15	S. No. Ingredient	Quantity (per serving)
	1. Ispaghula powder	1.50 g
	2. Triphala powder	1.20 g
	3. Dextrose	8.00 g
	4. Purified water	q.s. (lost in processing)
20	5. Sodium saccharin	0.01 g

Procedure:

- i) Ispaghula powder, Triphala powder and a part of Dextrose were mixed.
- ii) Sodium saccharin was dissolved in Purified water.
- 25 iii) The material of step (i) was granulated using the material of step (ii) to obtain the granules which were then dried.
- iv) The material of step (iii) was passed through #30 mesh sieve to yield the desired granules which is then provided in a suitable package.

Example-6

30	S. No. Ingredient	Quantity (per serving)
	1. Triphala extract	0.65 g
	2. Lactulose	15.00 g
	3. Peppermint oil	0.05 ml

4.	Fennel oil	0.03 ml
5.	Purified water	q.s. (lost in processing)
6.	Glycirrhizin	0.01 g

Procedure:

- 5 i) Triphala extract and a part of Lactulose were mixed.
 ii) Peppermint oil and Fennel oil were dissolved in ethanol.
 iii) Remaining part of Lactulose and Glycirrhizin were dissolved in Purified water.
 iv) The material of step (ii) was added to material of step (iii) with continuous stirring.
- 10 v) The material of step (i) was granulated using the material of step (iv) to obtain granules which were then dried.
 vi) The material of step (iii) was passed through #30 mesh sieve to yield the product.

15 **Example-7**

S. No.	Ingredient	Quantity (per serving)
1.	Triphala powder	2.0 g
2.	Maltitol	12.0 g
3.	Lactobacillus	10 ⁶ CFU
20 4.	Ginger oil	2.0 ml
5.	Sodium saccharin	0.008 g

Procedure:

- i) Triphala powder and a part of Maltitol were mixed together.
 ii) Remaining part of Maltitol, Sodium saccharin, Lactobacillus and Ginger oil
 25 were mixed together.
 iii) The material of step (i) and the material of step (ii) were then mixed thoroughly.
 iv) The material of step (iii) was passed through #30 mesh sieve to yield the powder.

30 **Example-8**

S. No.	Ingredient	Quantity (mg/tablet)
1.	Triphala extract	325.0
2.	Polycarbophil	80.0

	3.	Sorbitol	400.0
	4.	Docusate sodium	50.0
	5.	Citric acid	1.0
	6.	Purified water	q.s. (lost in processing)
5	7.	Aspartame	1.0
	8.	Magnesium stearate	9.0

Procedure:

- i) Triphala extract, Polycarbophil and Sorbitol were mixed.
- ii) Docusate sodium and Citric acid were dissolved in Purified water.
- 10 iii) The material of step (i) was granulated using the material of step (ii) to obtain the granules which were then dried.
- iv) The material of step (iii) was passed through #30 mesh sieve and mixed with Magnesium stearate sifted through #40 mesh sieve.
- v) The material of step (iv) were compressed into tablets.

15

Example-9

S. No.	Ingredient	Quantity (mg/tablet)
	1. Triphala extract	325.0
	2. Mannitol	220.0
20	3. Simethicone	125.0
	4. Calcium phosphate tribasic	40.0
	5. Docusate sodium	50.0
	6. Citric acid	1.0
	7. Purified water	q.s. (lost in processing)
25	8. Aspartame	1.0
	9. Colloidal silicon dioxide	7.0

Procedure:

- i) Triphala extract, Mannitol, Simethicone and Calcium phosphate tribasic were mixed.
- 30 ii) Docusate sodium, Citric acid and Aspartame were dissolved in Purified water.
- iii) The material of step (i) was granulated using the material of step (ii) to obtain the granules which were then dried.

- iv) The material of step (iii) was passed through #30 mesh sieve and mixed with Colloidal silicon dioxide sieved through #40 mesh sieve.
- v) The granules were compressed into tablets.

5 Example-10

S. No.	Ingredient	Quantity (g/100 ml)
1.	Triphala extract	13.00
2.	Bisacodyl	0.01
3.	Magnesium hydroxide	1.20
10 4.	Mannitol	6.05
5.	Sodium carboxymethyl cellulose	1.20
6.	Methyl paraben	0.75
7.	Propyl paraben	0.15
8.	Flavoring agent	0.03
15 9.	Acesulfame potassium	0.05
10.	Ethanol	q.s. (lost in processing)
11.	Purified water	q.s. to 100 ml

Procedure:

- i) Triphala extract, Bisacodyl, Magnesium hydroxide and Mannitol were mixed.
- 20 ii) Propyl paraben and the Flavoring agent were dispersed in Ethanol with stirring.
- iii) Sodium carboxymethyl cellulose, Methyl paraben and Acesulfame potassium were dispersed in Purified water.
- iv) The material of step (ii) was added to the material of step (iii) with stirring.
- v) The material of step (i) was added to the material of step (iv) with continuous
- 25 stirring to obtain a homogeneous dispersion.

Example-11

S. No.	Ingredient	Quantity (mg/tablet)
1.	Triphala extract	325.0
30 2.	Senna powder	300.0
3.	Maltodextrin	340.0
4.	Sodium cyclamate	11.5
5.	Sodium bicarbonate	68.5

6.	Tartaric acid	110.0
7.	Flavoring agent	0.025
8.	Ethanol	q.s. (lost in processing)
9.	Demineralized water	q.s. (lost in processing)

5 **Procedure:**

- i) Triphala extract, Senna powder, Maltodextrin and Sodium cyclamate were mixed together and sieved.
- ii) The mixture of step (i) was kneaded with a mixture of Ethanol and Demineralized water, granulated and dried.
- 10 iii) Sodium bicarbonate, Tartaric acid, and the Flavoring agent were mixed and sieved to give a mixture.
- iv) The mixture obtained in step (ii) and (iii) are mixed together and compressed into effervescent tablets.

15 **Example-12**

S. No.	Ingredient	Quantity (g/sachet)
1.	Triphala powder	2.50
2.	Lactulose	11.00
3.	Calcium hydroxide	0.10
20 4.	Sodium saccharin	0.01
5.	Peppermint oil	0.06 ml
6.	Orange oil	0.04 ml

Procedure:

- i) Triphala powder, Lactulose and Calcium hydroxide were mixed.
- 25 ii) The powder of step (i) was screened on a #80 mesh sieve, and to it, were added Sodium saccharin, Peppermint oil and Orange oil, and mixed.
- iii) The mixture was filled into sachets.

Example-13

S. No.	Ingredient	Quantity (per serving)
1.	Triphala extract	0.65 g
2.	Senna	1.0 g
3.	Dextran	2.0 g
4.	Talcum	0.5 g

	5.	Gum acacia	0.1 g
	6.	Ethanol	q.s. (lost in processing)
	7.	Purified water	q.s. (lost in processing)
	8.	Peppermint oil	0.04 ml
5	9.	Sodium saccharin	0.02 g

Procedure:

- i) Triphala extract, Senna and Dextran were sifted through #30 mesh sieve and mixed together.
- ii) Gum acacia and Sodium saccharin was dispersed in Purified water by stirring.
- 10 iii) Peppermint oil was dissolved in ethanol and mixed with the material of step (ii).
- iv) The material of step (i) was granulated by using the material of step (iii) to obtain granules.
- v) The granules were dried using fluidized bed dryer.
- vi) The dried granules were then mixed with Talcum thus yielding the final product.

Example-14

	S. No.	Ingredient	Quantity
	1.	Flour (#30 mesh passed)	100.0 g
20	2.	Ispaghula husk (#30 mesh passed)	100.0 g
	3.	Triphala extract	32.5 g
	4.	Lactulose liquid	200.0 ml
	5.	Shortening (fat)	120.0 g
	6.	Cocoa powder	10.0 g
25	7.	Baking powder	2.0 g
	8.	Liquid glucose	5.0 g
	9.	Milk powder	5.0 g
	10.	Vanilla essence	2.0 ml
	11.	Almond essence	1 drop

30 Procedure:

- i) Shortening (fat) and Lactulose were tilled together very lightly until a fluffy consistency was obtained.
- ii) Liquid glucose was added to step (i) and mixed.

- iii) Flour, Ispaghula husk and Triphala extract were sifted through a #30 mesh sieve and the fraction passing through the sieve was collected.
- iv) Cocoa powder, Baking powder, Milk powder, Vanilla essence and Almond essence were mixed with the material of steps (ii) & (iii).
- 5 v) The mixture of step (iv) was made into smooth & soft dough, rolled into required thickness and cut into desired size and baked at optimum temperature to obtain biscuits.

Example-15

10	S. No. Ingredient	Quantity (g)
	1. Ispaghula powder	0.120
	2. Maltodextrin	1.669
	3. Domperidone	0.01
	4. Sodium cyclamate	0.115
15	5. Sodium bicarbonate	0.7
	6. Tartaric acid	1.12
	7. Flavoring agent	0.025
	8. Ethanol	q.s. (lost in processing)
	9. Demineralized water	q.s. (lost in processing)

20 Procedure:

- i) Ispaghula powder, Maltodextrin, Domperidone and Sodium cyclamate were mixed together and sieved.
- ii) The mixture of step (i) is kneaded with a mixture of Ethanol and Demineralized water, granulated and dried.
- 25 iii) Sodium bicarbonate, Tartaric acid, and the Flavoring agent are sieved and mixed well.
- iv) The mixture obtained in step (ii) and (iii) are mixed together and compressed into effervescent tablets.

30 Example-16

S. No. Ingredient	Quantity (g)
1. Ispaghula husk	3.50
2. Lactulose	10.00

3.	Purified water	q.s. (lost in processing)
4.	Sodium saccharin	0.01
	Total	13.51

Procedure:

- 5 i) Ispaghula husk and a part of Lactulose were mixed.
- ii) Remaining part of Lactulose and Sodium saccharin were dissolved in Purified water.
- iii) The material of step (i) was granulated using the material of step (ii) to obtain the granules which were then dried.
- 10 iv) The material of step (iii) was passed through #30 mesh sieve to yield granules.

Example-17

S. No.	Ingredient	Quantity
	1. Lactulose powder	215.0 g
15	2. Triphala extract	32.5 g
	3. Flour	200.0 g
	4. Shortening (fat)	110.0 g
	5. Salt	1.0 g
	6. Milk	60 ml
20	7. Milk powder	10.0 g
	8. Cocoa powder	10.0 g
	9. Chocolate Chips	100.0 g
	10. Vanilla essence	3 ml
	11. Almond essence	1 drop
25	12. Baking powder	4.0 g

Procedure:

- i) Shortening (fat) is tilled lightly until a fluffy consistency is obtained.
- ii) Add Milk to step (i) & stirred continuously to give a creamy consistency.
- iii) Add Vanilla & Almond essence to step (ii) and mix.
- 30 iv) Mix Triphala extract, Lactulose powder, Flour, Salt, Milk powder, Cocoa powder, Baking powder & Chocolate Chips uniformly & add to step (iii) and make smooth & soft dough.

- v) Roll the dough to required thickness & cut to desired size and bake at optimum temperature to obtain biscuits.

Example-18

	S. No. Ingredient	Quantity
5	1. Flour	100 g
	2. Husk (mesh no.30)	100 g
	3. Lactulose liquid	200 ml
	4. Shortening (fat)	120 g
10	5. Cocoa powder	10 g
	6. Baking powder	2 g
	7. Liquid glucose	5 g
	8. Milk powder	5 g
	9. Vanilla essence	2 ml
15	10. Almond essence	1 drop

Procedure:

- i) Shortening (fat) and Lactulose are tilled together very lightly until a fluffy consistency is obtained.
- ii) Add Liquid glucose to step (i) & mix again.
- 20 iii) Sift Flour and Husk through a sieve of mesh no. 30.
- iv) Mix Cocoa powder, Baking powder, Milk powder, Vanilla essence and Almond essence, and mix with step (ii) & (iii).
- v) The mixture of step (iv) is made into smooth & soft dough, rolled into required thickness and cut into desired size and baked at optimum temperature.

We claim:

1. A novel composition comprising at least one bowel evacuant as the active agent and a saccharide component, optionally with at least one component selected from a group comprising antacid, stool softener, antifatulent, prokinetic, anti-emetic
5 and tonifier, and optionally one or more excipient(s).
2. A composition according to claim 1, wherein the bowel evacuant is a laxative or a purgative or mixtures thereof.
- 10 3. A composition according to claim 2, wherein the laxative is selected from a group comprising bulk laxatives such as ispaghula powder, methylcellulose, polycarbophil, malt soup extract, ethulose, sterculia, linseed, triticum, or mixtures thereof; osmotic laxatives such as magnesium carbonate, magnesium oxide, magnesium peroxide, magnesium sulfate, mineral salts in combination, sodium
15 sulfate, pentaerithrityl, macrogol, glycerol, sodium phosphate, magnesium citrate, sodium tartrate, or mixtures thereof; carbon dioxide releasing laxatives such as potassium bitartrate, sodium bicarbonate, or mixtures thereof.
4. A composition according to claim 2, wherein the purgative is selected from a
20 group comprising casanthranol, cascara, aloe, castor oil, dehydrocholate, phenolphthalein, senna, sennosides, sodium picosulfate, dantron, bisoxatin, used either alone or in combination thereof.
5. A composition according to claim 1, wherein the saccharide component is selected
25 from a group comprising lactulose, lactitol, sorbitol, mannitol, maltodextrin, dextran, sucrose, maltitol, dextrose, or mixtures thereof.
6. A composition according to claim 1, wherein the composition comprises ispaghula
30 as the bowel evacuant, lactulose as the saccharide component, triphala as the tonifier, optionally with one or more excipients.
7. A composition according to claim 1, wherein the composition comprises ispaghula and triphala as bowel evacuants and lactulose as the saccharide component.

optionally with at least one component selected from a group comprising stool softener, antiflatulant, antacid, anti-emetic and prokinetic, and one or more excipients.

- 5 8. A composition according to claim 1, which comprises triphala as the bowel
evacuant and lactulose as the saccharide component, optionally with at least one
component selected from a group comprising peppermint, fennel, ajwain, mentha
extract and lactobacillus optionally with at least one antacid and/or an antiflatulant
and/or a prokinetic, and one or more excipients.
- 10
9. A composition according to claim 1, wherein the composition is in the form of
tablets, minitablets, capsules, pellets, granules, patches, powders, sachets or
liquids.
- 15 10. A composition according to any of the preceding claims which is useful as a
pharmaceutical or a dietary supplement.
11. A composition according to any of the preceding claims which is highly effective
in the management of constipation including prophylaxis and/or amelioration
and/or treatment of constipation and associated disorders such as gas, bloating,
20 cramps, acidity, irritation, abdominal pain and discomfort thus providing a better
relief to the user.
12. A composition according to any of the preceding claims 1-10 which is useful as a
25 dietary supplement to normalize bowel functions and provide relief from
particularly constipation and other associated disorders.
13. A composition according to any of the preceding claims 1-10 which is useful in
the treatment and/or management of diseases or disorders of the bowel primarily
30 associated with constipation, diarrhea or indigestion.
14. A process of preparation of the composition according to claim 1, which
comprises mixing the active agent(s) and saccharide component optionally with at

least one component selected from a group comprising antacid, stool softener, antifatulant, prokinetic, anti-emetic and tonifier, and one or more excipient(s) and formulating into a suitable dosage form.

- 5 15. A method of using the composition according to claim 1, which comprises administering to a subject in need thereof an effective amount of the composition.
- 10 16. A method according to claim 15, wherein the composition according to claim 1 is useful for prophylaxis and/or amelioration and/or treatment of constipation and associated disorders such as gas, bloating, cramps, acidity, irritation, abdominal pain and discomfort.
- 15 17. A method according to claim 15, wherein the composition according to claim 1 is useful as a dietary supplement to normalize bowel functions and provide relief from particularly constipation and other associated disorders.
- 20 18. A method according to claim 15, wherein the composition according to claim 1 is useful in the treatment and/or management of diseases or disorders of the bowel primarily associated with constipation, diarrhea or indigestion comprising administering to a subject in need thereof a composition according to claim 1.
- 25 19. Use of a composition according to claim 1 for prophylaxis and/or amelioration and/or treatment of constipation and associated disorders such as gas, bloating, cramps, acidity, irritation, abdominal pain and discomfort.
- 30 20. The pharmaceutical compositions substantially as herein described and illustrated by the examples.
21. The processes for the preparation of pharmaceutical compositions substantially as herein described and illustrated by the examples.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN 2006/000462

A. CLASSIFICATION OF SUBJECT MATTER IPC⁸: A61K 36/68 (2006.01); A61K 47/36 (2006.01) 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) IPC⁸: 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) WPI, EPODOC, TXTE, XPESP, NPL, medline		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6187753 B1 (NOLL et al.) 13 February 2001 (13.02.2001) <i>column 6, lines 15-31; claim 1</i> --	1-3,5,9,14-19
X	EP 1340431 A1 (THE SWEET LIFE, INC.) 3 September 2003 (03.09.2003) <i>claims 1-3,8,16</i> --	1-3,5,9,14
X	US 4459280 A (COLLIOPOULOS et al.) 10 July 1984 (10.07.1984) <i>examples 1,4; claims</i> --	1-3,5,9,14
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> 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
Date of the actual completion of the international search 22 March 2007 (22.03.2007)		Date of mailing of the international search report 18 April 2007 (18.04.2007)
Name and mailing address of the ISA/ AT Austrian Patent Office Dresdner Straße 87, A-1200 Vienna Facsimile No. +43 / 1 / 534 24 / 535		Authorized officer KRENN M. Telephone No. +43 / 1 / 534 24 / 435

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN 2006/000462

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1997/006808 A1 (OLINGER Ph.) 27 February 1997 (27.02.1997) <i>claims 1,8</i>	1-3,9,14-19
E	WO 2007/013093 A2 (PRAKASH S.) 1 February 2007 (01.02.2007) <i>page 11, line 22-page 12, line 9; claim 1</i>	1-5,9,14-19

Continuation of first sheet**Continuation 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:

Claims Nos.: 15-19 because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 15-19 refer to a method of treatment of the human/animal body, a search has been carried out on the basis of the alleged effects.

Claims Nos.: 10-13,21,22 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:

The formulation "composition ... useful as ..." (claims 10-13) has no concrete technical meaning; it should be replaced by "composition for treating ..."; then it will be part of the report.

Claims (claims 21,22) shall not rely, in respect of the technical features of the invention, on references to the description (see PCT Rule, Article 6.2).

Continuation No. IV:**Text of the abstract****(Continuation of item 5 of the first sheet)**

Laxative composition comprising ispaghula, a saccharide component and optionally triphala mixed with optionally one or more excipient(s). Also provided are a process and a method of using such compositions. The compositions of the present invention are useful as pharmaceuticals or dietary supplements and are highly effective in the overall management of constipation and associated disorders thus providing a better relief to the user.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/IN 2006/000462

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