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Formulation and evaluation of poly herbal drugs powder by using antacid and anti-ulcer treatment

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Abstract

In the present study, poly-herbal powder was developed by using some traditional herbs having the antiulcer & antacid activity of a polyherbal formulation prepared by the combination of herbs such as Moringa leaves, ginger, garlic, coriander, eucalyptus, cinnamon, Amla and pomegranate to standardize the formulation. The polyherbal powder was prepared by mixing the raw drugs in accurate amount and then it was standardized. Polyherbal formulation of powder was analogized with sodium bicarbonate. The formulation when compared to standard drug highlighted the same acid neutralizing capacity. Through our present study, we concluded that the polyherbal formulation can be used as herbal antacid. The powder showed similar action as standard drug sodium bicarbonate. The formulation can be used to treat condition of gastro esophageal reflux disease, and, astringent acid neutralization, hyperacidity and GIT problems and activity that is desirable for the treatment of gastric ulcer. The formulation containing the powder herbs showed significant decrease in the ulcer index.

Keywords: Antacid, Antiulcer activity, polyherbal powder formulation, acid neutralizing capacity, sodium bicarbonate, standardization

Introduction

Gastric ulcer affects about 60% of the adults and about 80% of the child population in the tropical countries. Gastric and duodenal ulcers, gastro esophageal reflux disease are the gastrointestinal disorders sharing a common abnormality. The therapy for these disorders is directed at the correction of an apparent imbalance between the acid and pepsin activity and the mucosal resistance. The success of the therapy is measured in terms of ulcer healing, symptom control, relapse rate etc. Herbal compounds have been used for a variety of the disorders of the gastrointestinal tract. The herbal drugs are considered to be safe for use, easily available at cheaper cost and produce minimal side effects. The herbs Moringa leaves, ginger, garlic, coriander, eucalyptus, cinnamon, Amla and pomegranate, are reported in classical Ayurvedic texts to possess anti-phlogistic activity, astringent activity and acid neutralization activity that is Desirable for the treatment of gastric ulcer. Moringa leaves when it comes to stomach disorders the list could be endless and it seems like you need different type of medicine to deal with each of the condition. Well, some studies have proven that taking Moringa leaves extract has the same effect as taking antacids and antihistamines. So, what is the point of taking stuff that is harmful for your liver while Moringa leaves extract are not only natural unlike chemical-based drugs but also promote healthy liver while taking care your stomach disorders. Ulcerative colitis is one more example of stomach disorder that could be cured by taking Moringa leaves extract. Research studies have been especially conducted to proof that some contents found in Moringa leaves extract could act as potent Prednisolone. However, that kind of drug only takes care the condition by reducing the ulceration while Moringa leaves extract is not stopping there because Moringa leaves are containing some antibacterial agents that could prevent further infection caused by bacteria that could lead to condition like diarrhea. Ginger powder defines a peptic ulcer as a sore in the lining of your stomach or duodenum. They are most often Ulcers can be quite painful, so you may want to turn to medication for ulcer relief. Home remedies involve using acid reducing medications such as ranidine (Zantec) or famotidine (Pepcid) that are available over the counter.

If herbs for ulcers aren't providing the quick ulcer pain relief you're looking for, you can also turn to over-the-counter acid-neutralizing medications, such as Rolaids or Tums. They'll provide temporary relief but as the stomach produces more acid, you can expect the pain to return within an hour or two. *Emblica officinalis* are tannin containing compounds. These have a property of forming a complex with the proteins. This complex has been proved to be resistant to the photolytic enzymes. These properties that these drugs possess and the strategies, that have been put forth, for the treatment of gastric ulcers prompted for the preparation of polyherbal formulation containing the above said herbs and minerals.

Acid secretion in stomach leads to breakdown of food during digestion. Excessive secretion of acid in stomach prompts irritative sensation, heartburn in stomach lining, GIT disturbances and discomfort¹. The pH of stomach acid is 1-2. The acid in stomach is readily helpful in activation of digestive enzymes useful for breakdown of long chain amino acids. Acidity in stomach leads to a condition known as gastro esophageal reflux disorder. In the condition of GERD, the liquid contents in the form of mixed digestive juices drive back to the esophageal lining causing condition of heartburn and other irritation in gastrointestinal tract. Acidic food, alcohol, smoking, stress, drugs, less water intake, lack of fibers in diet, irregular routine, junk food and disturbed biological clock are the various reasons for causes of GERD². Herbal antacids are the agents that are useful in decreasing the acidic secretion in case of hyperacidity by use of medicinal plants. World health organization estimated that approximately 80% of population uses herbal and traditional medicines for primary choice in healthcare. Herbal medicines are safe, easily available, with less or no side effects. Herbal antacids are used to treat the hyper acidic condition in stomach. Various herbal medicines and plant extracts were used to attain a condition to treat hyper acidic condition. As the synthetic antacids cause various side effects and drug interactions, the herbal medicaments have become a safe and efficacious option to treat acidity in

stomach lining. Hence, in the present study we attempted to carry out biological standardization, phytochemicals screening and evaluation for antacid activity of polyherbal formulation by evaluating the acid neutralizing capacity of the formulation by the help of titration³.

Plant Materials

Herbal antacid & antiulcer was formulated in the form of powder by combination of a few effective herbs that have a potential to treat GERD. Some herbs were selected with the tendency to neutralize acid in the stomach to formulate the powder. The plant materials such as dried leaves of *Moringa* & eucalyptus, dried rhizomes of *Zingier officinale*, fresh fruits of *Emblica officinalis*, ripe bulbs of *Allium sativum* and dried inner bark of *Cinnamomum zeylanicum* were procured from local market, Vijayawada and the fresh leaves of *Eucalyptus globules* were collected from the medicinal garden, Vikas college of Pharmacy, Vissannapeta. All these herbs were authenticated by microscopic methods in Pharmacognosy Lab.

Preparation of dry herbal powder extracts

Accurately weighed about 100g of the herbs *Moringa* leaves, ginger, garlic, coriander, eucalyptus, cinnamon, Amla and pomegranate powder passed individually through 120# mesh separately and macerated separately with 95% of ethyl alcohol for 4 days. Then it was filtered and the filtrate was evaporated to dryness (at a temperature not to exceed 50°C) when gummy mass was obtained. It was further dried at a temperature not to exceed 50°C in a vacuum drier. The powder obtained was passed through 120#. Then the equal quantities of the powder obtained from these herbs were mixed to get the herbal powders

Preparation of triphala powder

The individual powders of the (*Moringa*, *Eucalyptus* and *Emblica officinalis*) herbs after passing through 120# was mixed in mortar to give triphala powder.



Fig 1: powders of Cinnamon, coriander, Moringa leaves

Preparation of Polyherbal powder

All the plant materials were thoroughly washed, dried and finely powdered. The finely powdered raw materials were passed through sieve number 40 and 1g of each of the individual drugs were weighed and mixed in appropriate

ratio (1:1:1:1:1). Black salt was added to enhance the taste and acceptability to consumer. The powder was packed in airtight container. The formula composition of the polyherbal powder is mentioned in Table 1.



Fig 2: Powders of Eucalyptus, Ginger, Amla.



Fig 3: powder of Pomegranate Peel Powder

Standardization of Polyherbal Powder Determination of pH

The pH of 1% solution of formulated polyherbal powder was identified by pH meter.

Determination of Ash Values

Total Ash Value

2g of powder was weighed accurately in a previously ignited silica crucible. The material was ignited at temperature of 500-600°C until it turns white indicating the absence of carbon. It was then cooled and total ash in mg per gram was calculated.

Acid Insoluble Ash Value

Using 25 ml of dilute hydrochloric acid, the half of the ash from the dish used for total ash washed into a 100 ml beaker. A wire gauge was placed over a Bunsen burner and boiled for five minutes. Filtered through an ash less filter paper, the residue was washed twice with hot water. Crucible was ignited in the flame, cooled and weighed. The acid insoluble ash of the crude drug was calculated with reference to the air-dried sample of the crude drug.

Water Insoluble Ash Value

To the crucible containing the other half of the total ash content, 25ml of hot water was added to it. Then, the whole material was filtered through ash less filter paper. The filter paper along with Insoluble matter was transferred to crucible and ignited to constant weight. The residue was then allowed to cool and weighed.

Determination of Extractive Value

Water Soluble Extractive Value

5g of powder was accurately weighed in conical flask. 25ml of water was added to it and kept for 24 hours shaking the flask occasionally. The contents were then transferred to china dish and evaporated to dryness on water bath, cooled and finally weighed.

Ethanol Soluble Extractive Value

5g of powder was accurately weighed in conical flask. 25ml of ethanol was added to it and kept for 24 hours shaking the flask occasionally. The contents were then transferred to china dish and evaporated to dryness on water bath, cooled and finally weighed.

Chloroform Soluble Extractive Value

5g of powder was accurately weighed in conical flask. 25ml of chloroform was added to it and kept for 24 hours shaking the flask occasionally. The contents were then transferred to china dish and evaporated to dryness on water bath, cooled and finally weighed.

Petroleum Ether Soluble Extractive Value

5g of powder was accurately weighed in conical flask. 25ml of petroleum ether was added to it and kept for 24 hours shaking the flask occasionally. The contents were then transferred to china Dish and evaporated to dryness on water bath, cooled and finally weighed.

Moisture Content (Loss on Drying)

The powder was placed in a weighing bottle. It was dried at 105°C in hot air oven and weighed after 15 minutes. When the weight of the formulation became constant, then percentage of water loss on drying was calculated.

Swelling Index

1g of formulation was placed in a stoppered measuring cylinder containing 9 ml water and kept aside for 24 hours. The swelling in the formulation was noticed and swelling index was calculated.

Preliminary Phytochemicals Screening

The crude petroleum ether, chloroform, ethanol and aqueous extracts were tested for the presence of alkaloids, steroids, tannins, saponin and glycosides using the standard procedures for preliminary phytochemicals screening.^{7, 11, 12} The qualitative results are expressed as (+) for the presence and (-) for the absence of phytochemicals.

Evaluation of Antacid Activity

The acid neutralizing capacity test was conducted at temperature $37 \pm 3^\circ\text{C}$. The pH meter was standardized using potassium dihydrogen phosphate, which is a standardized buffer. Magnetic stirrer was used to produce stirring rate of 300 ± 30 rpm. 2 gm of formulation and 2 ml of standard solution (sodium bicarbonate solution) were separately added to 70 ml distilled water in separate 250 ml volumetric flasks respectively. The solutions were stirred for 1 minute on magnetic stirrer. pH of both solutions was recorded. 30

ml of 0.1 N HCl were added in both the solutions and kept for stirring on magnetic stirrer for 15 minutes. The pH was recorded. 20 ml of conc. HCl was added in both the solutions and their pH was recorded. 0.5 N NaOH was titrated in the solutions for attaining a stable pH of 3.5, 4, 8, 9, 10

Evaluation of Anti-ulcer activity studies

Antiulcer activity studies on the formulations were carried out on albino rats of either sex weighing 200-250 g. The Histopathological studies were performed to ascertain the ulcer prevention. The rats were randomly divided into four groups, each group containing six animals. Group1 (Normal group) received only distilled water, Group2 (Control group) ulcer was induced, Group 3&4 were administered with the test formulation (FP-3& FE- 2) at the dose of 0.2 ml for seven consecutive days. Then the animals were fasted overnight. The fasted rats of groups 2, 3, 4 were administered 1ml of absolute alcohol. After 1 hr of alcohol administration, all the rats were anaesthetized and sacrificed by cervical dislocation. The stomachs were removed, and opened along the greater curvature, washed with normal saline and observed under microscope for the presence of the ulcers. The ulcers were scored as recorded in table 2: Mean ulcer score for each group was determined and ulcer index (UI) was calculated as under:

$$UI = \frac{(n. \text{lesion } 1) + (n. \text{lesion } 2) + (n. \text{lesion } 3) + \dots}{n. \text{Animals}}$$

Histopathological Studies

The tissue samples were fixed in 10% buffered formalin and

processed with paraffin wax. For this study 5mm sections were stained with haematoxylin and eosin. The extent and depth of the ulceration and hemorrhage were evaluated.

Results and Discussions

Standardization of Herbal powder

The formulated powder was a perfect blend of fine powder of herbs with antacid potential. The pH was determined so that the formulation itself does not produce any gastric irritation and 6.5 Was the estimated pH of formulated powder Since ashing process involves the complete oxidation of components of product, an increase in ash value indicates contamination, substitution and adulteration. The total ash value is an indicative of total amount of inorganic material after complete incineration.5 The Ash Values were calculated as: Total Ash Value-17.1%, Acid Insoluble Ash-3.40% and Water Insoluble Ash-13.70%. The extractive values aid in estimating the nature of phyto constituents and also helps in establishing the number of active constituents present in a medicinal plant material. The extractive values were calculated as: Water Soluble Extractive Value-7.20%, Ethanol Soluble Extractive Value-9.7%, Chloroform Soluble Extractive Value-2.40%, and Ether Soluble Extractive Value-1.60%. Thus, ethanol was the best solvent for extracting the phytoconstituents of the formulated powder. The moisture content was determined to establish any increase in weight caused by moisture absorption. Loss on Drying or moisture content of the formulated powder was 0.33%. The swelling index test was negative indicating the absence of the mucilaginous substances in the polyherbal powder. The results for standardization of powder are depicted in Table 2

Table 1: Formula Composition of Polyherbal powder

Drug	Biological Source	Part Used	Quantity
Moringa	<i>Moringa oleifera</i>	Leaves	1.g
Ginger	<i>Zingiber officinale</i>	Dried rhizomes	1g
Amla	<i>Emblica officinalis</i>	Fresh Fruits	1g
Garlic	<i>Allium sativum</i>	Ripe Bulb	1g
Eucalyptus	<i>Eucalyptus globulus</i>	Fresh Leaves	1g
Cinnamon	<i>Cinnamomum zeylanicum</i>	Dried Inner Bark	1g
Pomegranate	<i>Punica granatum</i>	Peel	1g

Table 2: Standardization of Polyherbal powder

S. No	Parameters	Polyherbal powder
1	Ph	6.5
2	Total Ash Value	17.1%
3	Acid Insoluble Ash	3.40%
4	Water Insoluble Ash	13.70%
5	Water Soluble Extractive Value	7.20%
6	Ethanol Soluble Extractive Value	9.7%
7	Chloroform Soluble Extractive Value	2.40%
8	Ether Soluble Extractive Value	1.60%
9	Moisture Content	0.33%
10	Swelling Index	Negative

Table 3: Ulcer score

0	Normal colored stomach.	0.5	Red coloration.
1	Spot ulcer	1.5	Hemorrhagic streaks
2	Ulcers equal to 3mm but less than 5mm	3	Ulcers greater than 5 mm

Table 4: Ulcer index

Group	Ulcer index
Control	1.01 ± 0.68
Ulcerated	8.68 ± 1.51
Treated	3.57 ± 2.14*
Treated	2.11 ± 1.07

Table 5: Preliminary Phytochemicals Screening of Polyherbal powder

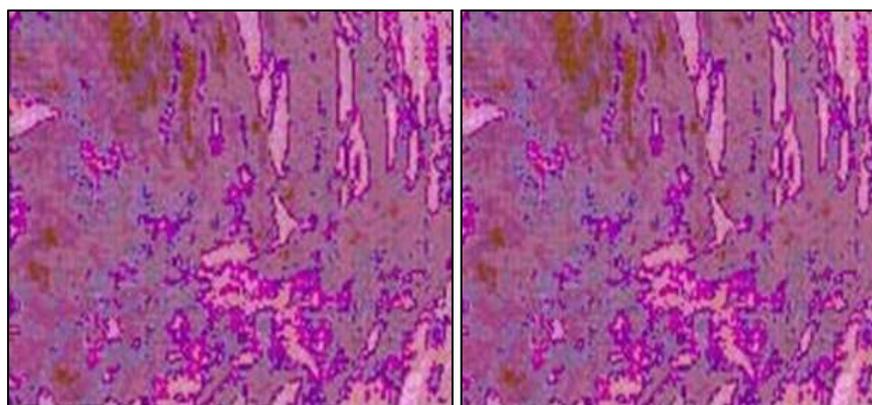
S. No	PC	IT	WE	AE	CE	PEE
1	Carbohydrate	Molish test	+	+	+	-
		Fehling's test	+	+	+	-
		Tollen's phloroglucinol test for Galactose	-	-	-	-
		Benedict's test	-	-	-	-
2	Starch	Iodine Test	+	+	-	-
3	Mucilage	Ruthenium Test	+	+	+	-
4	Protein	Xanthoprotein Test	-	-	-	-
		Millions test	-	-	-	-
5	Amino acids	Ninhydrin Test	+	-	-	-
6	Steroids	Salkowski reaction	+	-	-	+
7	Cardiac Glycosides	Legal test	-	-	+	-
		Raymond's test	-	-	-	-
		Test for deoxysugar (Keller-kilani test)	+	+	-	-
8	Anthraquinones glycosides	Borntrager's test	-	-	-	-
9	Saponin glycosides	Foam test	-	-	-	-
10	Alkaloids	Mayer's test	-	+	-	-
		Wagner's test	+	+	+	-
		Tannic acid test	+	+	-	+
11	Tannins	Lead acetate test	+	+	+	-
		5% FeCl ₃ test	+	+	-	-
		Acetic acid test	-	+	-	-
		Dil. HNO ₃ test	-	+	-	-
		Dil. NH ₄ OH test	-	+	-	-
12	Acidic Compounds	Sodium bicarbonate test	+	+	-	-
		Litmus paper test	+	+	+	-

PC: Phytoconstituents, IT: Identification Tests, WE: Water Extract,

AE: Alcohol Extract, CE: Chloroform Extract, PEE: Petroleum Ether Extract.

Table 6: Comparative antacid activity of Polyherbal powder and Sodium Bicarbonate

Steps	Test drug (Polyherbal powder)	Standard drug (Sodium Bicarbonate)
1	Powder + 70 ml distilled water.	Sodium Bicarbonate + 70 ml distilled water.
	pH- 6.5	pH- 6.8
2	powder + 70 ml distilled water + 30 ml 0.1 N HCl and Stirred for 15 minutes.	Sodium Bicarbonate + 70 ml distilled water + 30 ml 0.1 N HCl and stirred for 15 minutes.
	pH- 3.5	pH- 3.7
3	20 ml conc. HCl added to the above solution.	20 ml conc. HCl added to the above solution.
	pH- 2.4	pH- 2.5
4	The solution was titrated with 0.5 N NaOH for attaining pH- 3.5	The solution was titrated with 0.5 N NaOH for attaining pH- 3.5
	Volume of 0.5 N NaOH required- 50 ml	Volume of 0.5 N NaOH required- 46 ml

**Fig 3(a):** Normal mucosa**Fig 3(b):** Ulcerated mucosa

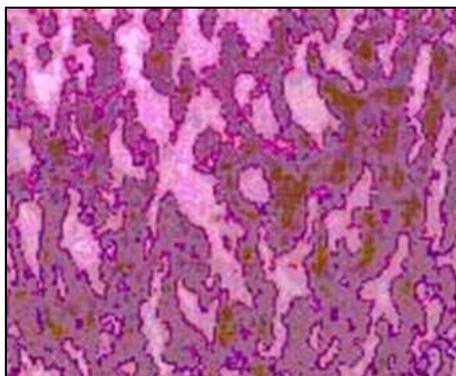


Fig 3(c): Treated mucosa.

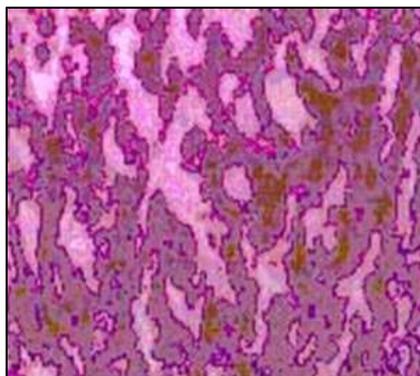


Fig 3(d): Treated mucosa

Preliminary Phytochemicals Screening

The results of the preliminary phytochemicals screening are mentioned in Table 3.

These identification tests led us to conclude that as the alcoholic extract responded positively to most of the chemical tests, thus maximum number of phytoconstituents is present in the alcoholic extract, followed by water, chloroform and petroleum ether extracts.

Evaluation of Antacid Activity

The equal ratio of each constituent herb in powder assisted it to attain the antacid activity similar to that of the standard drug: Sodium Bicarbonate. The formulated powder exhibited pH 6.5 in 70 ml distilled water while pH 6.8 was attained with sodium bicarbonate and 70 ml water. The pH was lowered to 3.5 and 2.4 respectively by addition of 30 ml of 0.1 N HCl with stirring for 15 minutes and then by adding 20 ml conc. HCl to powder and 70 ml water. Similarly, the pH of the standard was lowered respectively to 3.7 and 2.5. On titration with 0.5N NaOH the pH-3.5 was attained with both the test drug (formulated powder) as well as with the standard. Thus, it was concluded that the formulated polyherbal powder was as effective as the standard drug, i.e. sodium bicarbonate. Thus this powder can also provide relief from gastric problems.

Conclusion

Through this study it was found that Ginger, Garlic, Amla, Cinnamon and Eucalyptus powders formed a perfect harmonious combination in the form of where each drug acted in a synergistic manner to provide the maximum therapeutic effect for antacid activity. The powder formulated in this study has similar action as widely used antacid-sodium bicarbonate. This herbal powder could be used by patients having problems of GERD for improvements of physiology of GIT and digestive system to overcome the side effects of the synthetic medicines.

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Authors Contribution

Experimental design, guidance for the Research work and writing of this manuscript was done by Ch. Surya Kumari. Second author Subhranshu Panda supported to draft manuscript design and correction of data. Third author Asha Begam performed the experiments, analysed spectra and

interpreted the result. All authors played an equal role in completing this research work.

Conflict of Interests

All authors have none to declare

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Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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