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Research Article

Biological Standardization of Some Herbal Formulations for Antacid Activity

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Abstract

Herbal antacids are one of the major classes of over the counter drugs used by patient considering its safety. However, there are many herbal formulations in ayurvedic practice used for treatment of acidity which needs to be standardized. Hence, in present work we attempted to carry out biological standardization of some commonly used herbal formulations for antacid activity using *in vitro* methods viz-Acid-Neutralizing capacity and buffering capacity. From the results of present work, it may be concluded that HF 1 and HF 4 possess more antacid potential than HF 2 and HF 3 wherein HF 2 has shown varying results in acid neutralizing capacity and buffering capacity tests which may be associated with its herbal composition.

Keywords: Antacid; Herbal formulation; Standardization

Introduction

Acidity is a frequently occurring gastrointestinal disorder that can occur due to diverse reasons which is related to heartburn and gas formation in stomach. In acidity, gastro esophageal reflux disease (Urdhva Gata Amalpitta in Ayurveda) there is a movement of gastric acid from the stomach into the lower esophagus. Gastric acid is a digestive fluid formed in the stomach having a pH of 1 to 2. It is a mixture of hydrochloric acid, large quantities of potassium chloride and sodium chloride. Although there are a number of antacids and anti ulcer drugs, most of these have limitations, side effects and drug interactions [7]. Herbal antacids are one of the major classes of over the counter drugs used by patient considering its safety. However, there are many herbal formulations in ayurvedic practice used for treatment of acidity which needs to be standardized. Hence, in present study we attempted to carry out biological standardization of some polyherbal formulations for antacid activity using *in vitro* methods.

World Health Organization (WHO) estimated about 80% of the world population using herbal and other traditional remedy for their primary health care needs. Herbals are traditionally considered harmless and increasingly being consumed by people without prescription. However, some can cause health problems, some are not effective and some may interact with other drugs [3].

Herbal medicines, also known as botanical medicines or phytomedicines, uses herbs, herbal materials, herbal preparations, and finished herbal products that contain parts of plants or other plant materials as active ingredients. Herbal remedies are complex chemical combinations prepared from plants that are extensively used in health management in both urbanized and developing countries [1].

Materials and Methods

Materials

Herbal drugs were selected for the study on their traditional use in day to day life in Indian foods. The Selected herbal formulation were procured from Pharmanza Herbal Pvt. Ltd, Dharmaj region and labelled as HF 1, HF 2, HF 3 and HF 4. The composition of Selected Herbal antacid formulation is as follows Table 1.

Antacid activity

Acid-neutralizing capacity (ANC): The Acid-Neutralizing capacity test was carried out as per USP 29. The test was conducted at temperature 37±3OC. A pH meter was standardized using the 0.05M potassium biphthalate and 0.05M potassium tetraoxalate standardized buffers. Magnetic stirrer was used to produce the stirring rate of 300±30 rpm. 0.5gm of each formulation was transferred to 250ml beaker and 70ml distilled water was added to it. It was mixed with magnetic stirrer for 1min. Then 30ml 1.0N HCl was added to the test solutions with continuous stirring for 15min. Excess HCl was titrated with 0.5N NaOH to attain a stable pH of 3.5. The number 0f mEq of acid consumed was calculated by formula:

Total mEq= (30 × NHCL) - (VNaoH× NNAOH)

Where NHCl and NNaOH are normality of hydrochloric acid and sodium hydroxide respectively and VNaOH is volume of sodium hydroxide and the result were expressed as total mEq per gm of substance [8].

Buffering capacity (BC): A quantity of 2gm of finely ground powder or its equivalent of formulations was added to 100ml of 0.1N HCI and kept at 37°C with constant stirring. The pH of the mixture was determined after the intervals of 0.5, 2, 4, 6, 8 and 10 minutes. A quantity of 20ml of the mixture was then removed by a pipette and replaced by 20ml fresh 0.1N HCI. The process was repeated at 10 minutes interval until a pH below 2.75 was reached which shows that the buffering power of antacid was spent out [9].

Results and Discussion

The difficulty in the acceptance of the Ayurvedic formulation or herbal formulation is the lack of standard quality control profiles. The quality of herbal medicine i.e., the profile of constituents in the final

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Table 1: The composition of Selected Herbal antacid formulation.

HF1	HF2	HF3	HF4
Garcinia indica	*Garcinia indica*	*Garcinia indica*	*Garcinia indica*
Dughdh pashan	*Dughdh pashan*	*Dughdh pashan*	*Dughdh pashan*
Alovevera gel	*Alovevera gel*	*Alovevera gel*	*Alovevera gel*
-	*Foeniculum vulgare*	*Zingiber officinale*	*Curcuma longa*
Excipients	*Excipients*	*Excipients*	*Excipients*

Table 2: Acid neutralizing capacity of herbal formulations.

Formulation code	Meq of acid consumed
HF1	26.71
HF2	28.97
HF3	27.61
HF4	26.93

Table 3: Buffering capacity of some herbal formulations.

Time in min	pH of mixture Formulation			
	F1	F2	F3	F4
0.5	5.7	3.2	2.5	5.5
2	5.8	3.62	2.8	5.7
4	6	3.71	2.97	6.1
6	6.1	3	3.5	6.3
8	6.3	2.91	3.77	6.4
20-Oct	6.65	2.81	3.3	6.52
20-30	5.91	2.72	3.11	5.66
30-40	5.8	2.6	2.59	4.57
40-50	5.2	--	--	3.25
50-60	4.03	--	--	2.5
60-70	2.61	--	--	--
70-80	--	--	--	--
80-90	--	--	--	--

product has implication in efficacy and safety. Quality evaluation of plant materials and herbal preparation is a fundamental requirement of industry and other organization dealing with ayurvedic and herbal products. Now a day's most of the ayurvedic formulations are lacking in defined quality control parameters. FDA has made the quality control and GMP mandatory for ayurvedic formulation, which has been implemented from 1stJanuary 2003 [10].

Self-medication with herbal medicinal products is widespread. Self-medication with herbal medicinal products may provide a sense of control or psychological comfort for the patient. This is particularly evident in those patients for whom conventional medicines cannot provide any further benefits e.g. chronic conditions such as eczema, arthritis and acidity. There are a number of problems associated with herbal medicinal products, one of which is limited evidence of efficacy in the form of well-designed clinical trials. As there is not enough evidence produced by common scientific approaches to answer questions of safety and efficacy about most of the herbal medicines now in use, the rational use and further development of herbal medicines will be supported by further appropriate scientific studies of these products, and thus the development of criteria for such studies. In the light of the above, present study was undertaken to evaluate the antacid property of some commonly used polyherbal formulations [11].

FDA has introduced an in-vitro test to determine acid neutralization capacity of antacid products. *In vitro* test can approximate *in vivo* conditions with respect to acid neutralizing capacity, speed and duration of action and maximum buffering capacity of the antacid [9]. In the present investigation both the parameters: Acid Neutralizing Capacity (ANC) and Buffering Capacity (BC) have been employed to determine antacid activity. As per the ayurvedic physicians and chemists, the selected preparations are being prescribed for the antacid activity; undoubtedly these preparations have got some other uses too [11].

Acid neutralizing capacity and the buffering capacity of selected preparation were calculated and tabulated in (Table 1 and 2) respectively. In Acid neutralizing capacity test, HF 1-4 consumed significantly high amount of acid compared to blank (Table 1). On the basis of ANC, these products are ranked as HF 2>HF 4>HF 1>HF 3for their acid neutralizing capacity. In buffering capacity test, the time at which pH falls below 2.75 was used as measure of buffering capacity wherein HF 1 showed pH below 2.75 between 70-80 minute interval and HF 4 showed pH below 2.75 between 50-60 minute intervals (Table 2). HF 2 and FH 3 showed pH below 2.75 between 30-40 minute intervals. On the basis of BC, the products are ranked as HF 1>HF 4> HF 2= HF 3 for their buffer capacity.

Thus it may be concluded that HF 1 and HF 4 possess more antacid potential than HF 2 and HF 3 wherein HF 3 has shown varying results in acid neutralizing capacity and buffering capacity tests which may be associated with its herbal composition in which some herbs may be acting synergistically while other may be antagonistic inaction. Hence biological standardization is of prime importance in quality control of herbal medicine to establish its efficacy.

Conclusion

The present investigation revealed that the Herbal formulation of antacid gel posseses excellent antacid and antiulcerative activity. Antacid activity observed may be due to presence of therapeutic markers in prepared herbal formulation by acid neutralizing capacity showing very good antacid activity.

Thus, Herbal formulation possesses significant antcid activity and antiulcerative properties and it may be useful in the gastric acidity, heart burn treatment. The formulation is sugar free; it is significant in diabetic patient.

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