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Biological standardization of some polyherbal 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 study we attempted to carry out biological standardization of some commonly used polyherbal formulations for antacid activity using in vitro methods viz- Acid-Neutralizing capacity and buffering capacity. From the results of present study, it may be concluded that PHF 2 and PHF 3 possess more antacid potential than PHF 1 and PHF 4 wherein PHF 1 has shown varying results in Acid neutralizing capacity and buffering capacity tests which may be associated with its polyherbal composition in which some herbs may be acting synergistically while other may be antagonistic in action.

Key words: Antacid, Polyherbal formulations, Biological standardization.

INTRODUCTION

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. 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 [1-3].

Standardization of herbal formulations is essential in order to assess the quality of drugs, based on the concentration of their active principles and is a fundamental requirement of industry dealing with ayurvedic and herbal medicines [4]. Standardization is an important aspect for maintaining and assessing the quality and safety of the polyherbal formulation as these are combinations of more than one herb to attain the desire therapeutic effect [5].

The literature survey revealed studies on formulation and standardization of a polyherbal formulation (Artrex®) designed for the treatment of arthritis containing four botanicals , standardization of Madhumehari Churna (Baidynath) containing the mixture of eight herbal antidiabetic drugs, Pancasama Churna known to be effective in gastrointestinal disorder, Dashamularishta, a traditional formulation, used in the normalization of physiological processes after child birth, Gokshuradi Churna, Megni and Jawarish-e-Darchini [6]. However, there are many polyherbal formulations in market which needs to be standardized.

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.

MATERIALS AND METHODS

Materials:

Polyherbal (Ayurvedic) antacid formulations were selected for present study based on their sale and use. The Selected Polyherbal formulation were procured from Mankarnika Aushdhalaya in Pune region and labeled as PHF 1, PHF 2, PHF 3 and PHF 4.The composition of Selected Ayurvedic antacid formulation are as follows:

PHF 1(Churna)	PHF 2(Avaleha)	PHF 3 (Tablets)	PHF 4(Kadha)
Zingiber officinale	*Punica granatum*	*Shankh bhasma*	*Kirayata*
Piper nigrum	*Myristica fragrance*	*Shunthi (Zingiber officinale)*	*Kadu*
Piper longum	*Piper nigrum*	*Sajji-kshar suddha*	*Padawala*
Terminalia chebula	*Cinnamomum tamala*	*Garlic*	*Neem saal*
Terminalia belerica	*Cinnamomum, zeylanicum*	*Gopichandan*	*Pitta papda*
Emblica officinalis	*zingiber officinale*	*Binders*	*Adulsa*
Cyperus rotundus	*Piper longum*	*Excipients*	*Amla*
Black salt	*Aromaticum*	--	*Gulvel*
Elettaria cardamomum	*Sugar*	--	*Hirda*
Cinnamomum tamala	--	--	*Maka*
Syzygium aromaticum	--	--	*Behda*
lpomea turpethum	--	--	--
Sugar	--	--	--

Antacid activity:

A. Acid-Neutralizing Capacity (ANC):

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

Total mEq= (30 X N_{HCl})- (V_{NaoH} X N_{NaoH})

Where N_{HCl} and N_{NaOH} are normality of hydrochloric acid and sodium hydroxide respectively and V_{NaOH} is volume of sodium hydroxide and the result were expressed as total mEq per gm of substance [8].

B. Buffering Capacity (BC):

A quantity of 2 gm 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 20 ml 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 polyherbal formulation is the lack of standard quality control profiles. The quality of herbal medicine i.e. the profile of constituents in the final 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 1st January 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.

Further, in spite of the advancement in biomedical research, and the benefits derived by the society through them, the opposition to animal experiments always existed. By adopting an extreme moralistic standard, the animal activists look at animal researchers as cruel and corrupt, consumed by desire for ever more papers and grants. The fundamental pragmatic value of biomedical enquiry to both humans and other animals is the relief of human and animal suffering and the enhancement of opportunities for individual activity and well being. Considering the arguments of animal activists and constraint raised by animal ethical committee in vitro tests seems to be a better alternative for preliminary pharmacological experimentation of polyherbal formulations.

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.

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, PHF 1-4 consumed significantly high amount of acid compared to blank (Table 1). On the basis of ANC, these products are ranked as PHF 4> PHF 2 > PHF 3> PHF 1 for 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 PHF 2 showed pH below 2.75 between 70-80 minute interval and PHF 3 showed pH below 2.75 between 50-60 minute intervals (Table 2). PHF 1 and PFH 4 showed pH below 2.75 between 30-40 minute intervals. On the basis of BC, the products are ranked as PHF 2 > PHF 3> PHF 1= PHF 4 for their buffer capacity.

Table 1: Acid neutralizing capacity of some polyherbal formulations

Antacid formulations	mEq of acid consumed
PHF 1	26.27
PHF 2	26.91
PHF 3	26.65
PHF 4	28.22

Table 2: Buffering capacity of some polyherbal formulations

pH at time interval of minutes	Formulations			
	PHF 1	PHF 2	PHF 3	PHF 4
0.5	2.5	5.6	5.5	2
2	2.62	5.8	6	2.2
4	2.8	6	6.1	2.8
6	3.1	6.1	6.3	3.5
8	3.25	6.3	6.38	3.7
10-20	3	6.65	6.48	3.4
20-30	2.8	5.9	5.62	3.1
30-40	2.6	5.8	4.52	2.6
40-50	--	5.7	3.32	--
50-60	--	5	2.42	--
60-70	--	4.3	--	--
70-80	--	2.56	--	--
80-90	--	--	--	--

CONCLUSION

Thus it may be concluded that PHF 2 and PHF 3 possess more antacid potential than PHF 1 and PHF 4 wherein PHF 4 has shown varying results in acid neutralizing capacity and buffering capacity tests which may be associated with

its polyherbal composition in which some herbs may be acting synergistically while other may be antagonistic in action. Hence biological standardization is of prime importance in quality control of herbal medicine to establish its efficacy.

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