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FORMULATION, EVALUATION AND STANDARDIZATION OF POLYHERBAL CHURNA AS ANANTACID AND LAXATIVE

Dr. Abhijeet S. Kulkarni[1], Umesh D. Jirole[2], Anjali D. Yadav[3]*, Abhishek R. Mane[4] and Abhijeet M. Sutar[5]

Ashokrao Mane Institute of Pharmaceutical Science and Research, Save Dist. Kolhapur.

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***Corresponding Author**
Anjali D. Yadav
Ashokrao Mane Institute of Pharmaceutical Science and Research, Save Dist. Kolhapur.

ABSTRACT

A polyherbal churna (coarse powder) for antacid and laxative formulation prepared by the combination of herbs such as fennel, amla, ginger, cinnamon, ajowan, myrobalan and coriander to standardize and evaluate the formulation. Sodium bicarbonate was compared to polyherbal churna (coarse powder). The formulation when compared to standard drug highlighted the same acid neutralizing capacity (ANC). With the help of our formulation we studied that, some of disorders like hyperacidity, heartburn, indigestion and constipation can be diminished.

KEYWORDS: Sodium bicarbonate, churna (coarse powder), Antacid, Laxative, Standardization, Evaluation etc.

INTRODUCTION

Polyherbal churna is as a fine powder of drug or drugs in Ayurvedic system of medicine. Triphala churna, Trikatu churna, Drakeshadi churna and Sudarshana churna are some examples. Smaller the particle size greater is the absorption rate from GIT and hence the greater is bioavailability.[1] Herbal medicines are safe, easily available, with less or no side effects.[2] Gastric ulcer affects about 60% of the adults and about 80% of the child population in the tropical countries.[3] Acidity oftenly 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 (GERD) there is a movement of gastric acid from the stomach into the lower esophagus. Gastric acid is a digestive fluid that is formed in the stomach and has a pH of 1 to 2. It's a mix of hydrochloric acid, NaCL, and KCL in significant amounts.[4] Constipation is very common gastrointestinal disorder; it refers to the difficulty

in passing of stool.[5]

Types of Churnas[21]

These are solid dosage form of medicament meant for internal use.

These are classified into two different types, as following-

1] Simple Churnas - It contains only one medicine.

2] Compound Churnas - It contains two or more than two medicine.

Table No. 1: Marketed Product.

Marketed Products	Dosage Forms	Herbal Drugs
AVIPATTIKAR CHURNA[6]	Powder	Sounth, Amla, Nisoth, Mustak, Vaividang, Haritaki,Bibhitaki, Elaichi

A polyherbal churna (coarse powder) consists of herbs such as fennel, amla, ginger, cinnamon, ajowan, myrobalan and coriander drugs which useful to treat hyperacidity, heartburn, indigestion and constipation.[7]

In polyherbal churna (fine powder) consists of herbs such as following.

Fennel: Fennel is made from the dried mature fruits of the plant Foeniculum vulgare. It is used as carminative, aromatic, stimulant, expectorant and also used as flavoring agent. The two main type of fennel i.e 1) sweet fennel and 2) bitter fennel.[24]

Amla: Amla consists of dried as well as fresh fruits of the plant known as 'Emblica officinalis'. It's alaxative and part of the triphala and chyavanprash formulas. It has vitamin C and high fibre which helps in healing the injured stomach lining and Oesophagus.[17] Amla is sometimes used as a laxative to relieve constipation in piles. Amla Berry is ideal for calming mild to moderate hyperacidity.[26]

Ginger: Zingiber officinale's dried rhizomes, whole or chopped, are used to make ginger. It is used as a stomachic as well as an aromatic, carminative, stimulant, flavouring and motion sickness treatment agent. The properties of the root help with digestion and nutrition absorption.[17] Traditional medicine of India, also known as sunthi in ayurveda.[25]

Cinnamon: Cinnamon is made from the inner bark of Cinnamomum zeylanicum trees. It is used as carminative, stomachic, aromatic and mild astringent. Two main type of cinnamon i.e 1) Ceylon 2) cassia.[23]

Ajowan: Ajowan consists of dried ripe fruits of the plant 'Trychyspermum ammi'. It is used as carminative, antispasmodic, stimulant. Ajowan can increase the secretion of gastric acid, bile acids and activity of digestive enzyme.[22]

Myrobalan: Myrobalan consists of dried ripe fruits of 'Terminalia chebula'. It is used as laxative, stomachic, astringent and tonic. It is an ingredient of triphala used for treatment of variety of ailments. It is recorded in Illustrated Materia Medica; it is most common used in Tibetan Medicine and is also called the king of Tibetan Medicine. Tannin, as main active ingredient in myrobalan.[28]

Coriander: Coriander consists of dried ripe fruits of Coriandrum sativum. It is used as aromatic, stimulant stomachic, diuretic. Coriander is referred to as "kusthumbari" or "dhanayaka" in thaSanskrit literature; in hindi it is called Dhania, while Dhane in Benhali.[27]

Advantage of antacid[29]

1. This medication is used to treat the symptoms of too much stomach acid such as stomach upset, heartburn and acid indigestion.
2. It is also used to relieve symptoms of extra gas such as belching, bloating and feelings of pressure/discomfort in the stomach/gut. Simethicone helps break up gas bubbles in the gut. Aluminum and magnesium antacids work quickly to lower the acid in the stomach.
3. Liquid antacids usually work faster/better than tablets or capsules. This medication works only on existing acid in the stomach. It does not prevent acid production.

Disadvantage of antacid[29]

1. The magnesium in this product can cause diarrhea. Using an antacid that contains only aluminum along with this product can help control diarrhea. The aluminum in this product can cause constipation.
2. To minimize constipation, drink plenty of fluids and exercise. Diarrhea is more common with this product than constipation.

Advantage of laxative[30,31]

1. Laxatives have positive effects on your digestive health, helping relieve constipation and promoting regular bowel movements.
2. They're often used to treat constipation, a condition characterized by infrequent, difficult and sometimes painful bowel movements.

Disadvantage of laxative[30,31]

1. It is bland but very unpleasant to swallow because of oily consistency.
2. Small amount passes into the intestinal mucosa-is carried into the lymph may produce foreign body granulomas in the intestinal submucosa, mesenteric lymph nodes, liver and spleen.
3. While swallowing it may trickle into lungs cause lipid pneumonia.
4. Carries away fat soluble vitamins with it into the stools: deficiency may occur on chronic use.
5. Leakage of the oil past anal sphincter may embarrass.
6. May interfere with healing in the anorectal region. Thus, it should be used only occasionally.

PLAN OF WORK

- Objectives
- Relevance and Motivation
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➢ Plant Material

- Formulation of polyherbal powder
- Standardization of polyherbal powder

➢ Determination of Ash Values

- Total Ash Value
- Acid insoluble Ash Value
- Water insoluble Ash Value

➢ Determination of Extractive Value

- Water Soluble Extractive Value
- Ethanol Soluble Extractive Value
- Chloroform Soluble Extractive Value
- Moisture Content
- Swelling Index
- Evaluation

➢ Organoleptic Evaluation

- Appearance

- Colour
- Odour
- Taste

➢ Evaluation of Churna

- Bulk Density
- Tap Density
- Angle of Repose
- Compressibility\Carr's Index

▪ Result discussion
▪ Expected outcome
▪ Reference

OBJECTIVES

1. To reduce side effect of existing formulation of antacid and laxative.
2. To formulate effective dosage form to avoid digestive disorders.
3. To evaluate the prepared churna.
4. To promote herbal churna which have less side effects.

RELEVANCE AND MOTIVATION

In our society we observed that many people suffering from acidity, heartburn, indigestion and constipation problems. Allopathic drug may cause dose dependent rebound hyperacidity and milk-alkali syndrome .High dose calcium carbonate and sodium bicarbonate when taken together can cause a condition called milk-alkali syndrome; it causes headache, nausea, weakness etc. We can't prefer the Antacids for the children under age of 6 years. Antacids that contain aluminum hydroxide may cause constipation, aluminum-intoxication, osteomalacia and hypophosphatemia. Antacids that contain magnesium have a laxative effect that may cause diarrhea and in patients with renal failure they may cause increased magnesium levels in the blood, because of the reduced ability of the kidneys to eliminate magnesium from the body in the urine, to overcome these side effects we have motivated to prepared polyherbal churna of antacid and laxative.

NEED OF WORK

Some synthetic or chemical containing products may cause toxic effects to health like Zolinger Elson Syndrome and Sodium bicarbonate increases Na+ load may worsen edema

and CHF. The brands of antacids with calcium and aluminium may cause constipation or other side effects.

There are some advantages of using herbal products like having lesser side effects, they have low in cost, easily availability and easy to administration. We understand these factors and feel there is need to prepare herbal product which helps to improve health as well as reduce the side effects.

LITERATURE REVIEW

1) **Surbhi Sharma; et al; (2018)** In her study she performed a research of antacid in which they collected dried leaves of eucalyptus (Eucalyptus globulus), dried rhizomes of ginger (Zingier officinale), fresh fruits of amla (Emblica officinalis), ripe bulbs of garlic (Allium sativum) and dried inner bark of cinnamon (Cinnamomum zeylanicum), dried ripe fruits of fennel (Foeniculum vulgare), ajowan (Trychyspermum ammi) and myrobalan (Terminalia chebula).

2) **Patel P; et al; (2011)** They have performed a experiment on formulation of dried powder of Fennel, Amla, Ginger, Garlic, Cinnamon, Eucalyptus, Ajowan and Myrobalan. Pass all the powder separately through sieve No.80/ 120 and mixed all the powdered herbal drugs geometrically.

3) **Kokate C.K.; et al; (2011)** In this book they explained and performed the standardization of polyherbal churna various methods like determination of pH, total ash, acid insoluble ash value, water insoluble ash value, water soluble extractive value, ethanol soluble extractive value, chloroform soluble extractive value, moisture content and swelling index, we used the above parameters for our studies.

4) **Abhishek Bhardwaj; et al; (2017)** In his research it was observed that he performed all Preformulation studies like bulk density, tapped density, angle of repose, Carr's Index, Hausner's ratio and we also used the same parameters for our study.

METHODS AND MATERIALS

1) Plant Material

Herbal antacids and laxatives were created in the form of churna (coarse powder) by combining a few efficient herbs that might help with GERD, indigestion, hyperacidity and chronic constipation. The powder was made with botanicals that have a proclivity for neutralising gastric acid.

Plant materials such as dried leaves of ginger (Zingiber officinale), dried rhizomes of ginger (Zingier officinale), fresh fruits of amla (Emblica officinalis), dried inner bark of cinnamon (Cinnamomum zeylanicum), dried ripe fruits of fennel (Foeniculum vulgare), ajowan (Trychyspermum ammi), myrobalan (Terminalia chebula). In the Pharmacognosy Lab, all of these botanicals were authenticated using processes carried out under a microscope.[2]

2) Preparation of Churna

First clean, dry, churna and sieve through cloth, the drug's mentioned in the formula.[8] To make dried powders of fennel, amla, ginger, cinnamon, ajowan, myrobalan, and coriander, filter each powder individually through sieve No.80/120. Geometrically combine all of the powdered herbal medications. Now place the powder churna in a container that can be easily moved. Each 1gm drug weigh as the ratio (1:1:1:1:1:1:1:1)[2] It should be kept in an air tight container and It should be used within 6 months.[8] Appropriate formula mentioned in Table 5.

Fig.No. 1: Prepared herbal churna and weighed ingredients.

3) Standardization of Polyherbal Powder[8,9,10,11,12,13]

First upon standard operating procedure to operated and calibrated pH meter and activation of pH electrode.[15] Determination of pH. The pH of 1% solution of formulated polyherbal churna (coarse powder) was identified by pH meter.

4) Determination of Ash Values

4.1) Total Ash Value[18]

2g of churna (coarse powder) was weighed accurately in a previously ignited silica crucible. A temperature of 500-600°C was used to ignite the substance. The muffle furnace device,

which has a very high temperature, was used to determine the ash value present in the powdered sample. until itturns white, indicating that carbon is no longer present It was then cooled and total ash in mg per gram was calculated.

Total Ash value = $\frac{\text{Weight of total ash}}{\text{Weight of crude drug taken}} \times 100$

Fig.No.2: Silica crucible.

4.2) Acid Insoluble Ash Value[18]

In a 100 mL beaker, half of the ash from the total ash dish was washed with 25 mL weak hydrochloric acid. A wire gauge was boiled for five minutes over a Bunsen burner. The residue was filtered through an ash-free filter paper and rinsed twice with hot water. The crucible was heated, then cooled and weighed. With the air-dried sample of the crude drug as a reference, the acid insoluble ash of the crude drug was estimated.

Acid insoluble ash value = $\frac{\text{Weight of acid insoluble ash}}{\text{Weight of crude drug taken}} \times 100$

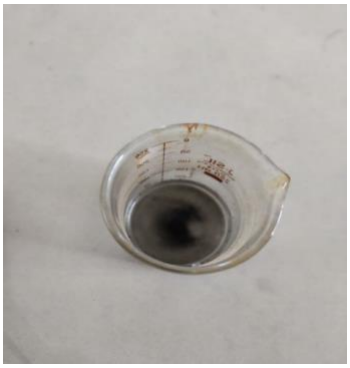

Fig. No. 3 Acid insoluble ash value.

4.3) Water Insoluble Ash Value[19]

The crucible containing the remaining half of the ash content received 25ml of hot water. The entire mixture was then filtered via ash-free filter paper. The insoluble components were placed in the crucible with the filter paper, which was then burned to a constant weight. After

that, the residue was allowed to cool before being weighed.

$$\% \text{ Yield} = \frac{\text{Weight of water extract} \times 100}{\text{Amount of drug taken}}$$

5) Determination of Extractive Value

Fig. No. 4: Pre – Formulation extractive value.

5.1) Water Soluble Extractive Value

In a conical flask, 5g of powder was accurately weighed. It was filled with 25ml of water and left for 24 hours, stirring the flask every now and then. The contents were then transferred to a porcelain plate, dried in a water bath and weighed.

5.2) Ethanol Soluble Extractive Value

In a conical flask, 5g of churna (coarse powder) was precisely weighed. It was then filled with 25ml of ethanol and left for 24 hours, stirring the flask occasionally. The contents were then transferred to a porcelain plate, dried in a water bath, and weighed.

5.3) Chloroform Soluble Extractive Value

In a conical flask, 5g of churna (coarse powder) was precisely weighed. 25ml of chloroform was added to it and kept for 24 hours shaking the flask occasionally. The contents were then transferred to a porcelain plate, dried in a water bath, and weighed.

Fig. No. 5 Water bath.

5.4) Moisture Content (Loss on Drying)[20]

The churna (coarse powder) was placed in a weighing bottle. It was dried in a hot air oven at 105°C for 15 minutes before being weighed Once the weight of the formulation had stabilised, the percentage of water loss on drying was estimated.

% Loss on Drying = Loss in weight in sample × 100

Weight of sample

Fig. No.6 Loss on drying.

5.5) Swelling Index

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

1) Organoleptic Evaluation[16]

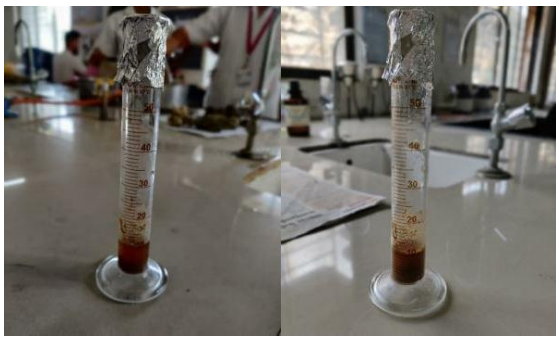

Fig. No. 7: Swelling index.

EVALUATION

Organoleptic evaluation refers to evaluation of formulation by colour, odour, taste,

1.1) Appearance - Churna (coarse powder)

1.2)Colour - Brown

1.3)Taste - Pungent

1.4)Odour - Characteristics.

2) Evaluation of Churna[12,14]

2.1) Bulk Density: 10g of churna (coarse powder) was taken in a graduated measuring cylinder and tapped on a wooden surface. Bulk density is calculated using this formula after that, chill it for at least 24 hours. We utilize a tap density volumetric flask to estimate bulk density, into which we place a 10g powder sample and compute bulk density using the formula below.

$$\text{Bulk Density} = \frac{\text{Weight of mass}}{\text{Bulk volume}}$$

2.2) Tap Density: Tap density of churna (coarse powder) was determined after 50 tapping with the help of tap density apparatus. We check the churna's tap volume and calculate the weight taken to thetap volume of the churna sampleto determine tap density. The formula is used to compute bulk density.

The following formula can be used for the determination of tap density.

$$\text{Tap Density} = \frac{\text{Weight of mass}}{\text{Tapped volume}}$$

2.3) Angle of Repose: The funnel method was used to determine the angle of repose. The churna (coarse powder) was allowed to flow through a funnel fixed on a stand to form a heap. The height and the radius give the angle of repose.

$$\text{Angle of Repose } (\theta) = h/r$$

$\theta = \text{Tan}^{-1}(h/r)$ Where, h = height of, r=radius of heap

2.4) Compressibility / Carr's Index

This is calculated using the formula

$$\text{Carr' Index} = \frac{\text{Bulk density (Tapped)} - \text{Bulk density (Untapped)}}{\text{Bulk density (Tapped)}} \times 100$$

2.5) Hausner's Ratio: The formula used to determine Hausner's ratio we use bulk density and tapdensity ratio. For the determination of Hausner' ratio following formula.

$$\text{Hausner's Ratio} = \frac{\text{Bulk density (Tapped)}}{\text{Bulk density (untapped)}}$$

RESULT AND DISCUSSION

1) Formulation Technique

Table 3: Formula of Polyherbal Churna.

Herbal Drugs	Plant Part	Quantity Given	Quantity Taken
Fennel	Dried ripe fruits	1gm	3 gm
Amla	Fresh fruits	1gm	3gm
Ginger	Dried rhizomes	1gm	3 gm
Cinnamon	Dried inner bark	1gm	3 gm
Ajowan	Dried ripe fruits	1gm	3 gm
Myrobalan	Dried ripe fruits	1gm	3 gm
Coriander	Dried ripe fruits	1gm	3 gm

2) Standardization of Polyherbal Churna

We developed a perfect churna of herbs with antacid properties, which we dubbed churna (coarse powder). The pH was set so that the formulation did not cause any gastrointestinal irritation, and the pH of the formed churna was estimated to be 5.84. (coarse powder). An increase in ash valuesuggests contamination, replacement or adulteration because the ashing process includes the complete oxidation of product components. After complete burning, the total ash value indicates the total amount of inorganic material. 5 The total ash value was 8.5 percent, the acid insoluble ash value was 7% and the water insoluble ash value was 23.50 percent. The extractive values are used to determine the kind of phytocomponents as well as the amount of active chemicals in a medicinal plant material. The extractive values were calculated as: Water Soluble Extractive Value-3.90%, Ethanol Soluble Extractive Value-3. Chloroform Soluble Extractive Value-410 percent, 35 percent, thus ethanol was the best solvent for extracting the phytoconstituents of the formulated powder. The moisture content was evaluated in order to assess any weight gain due to moisture absorption. Loss on Drying or moisture content of the formulated powder was 0.32%. The swelling index test was negative indicating the absence of the mucilaginous substances in the polyherbal powder. The resultsof powder standardization are shown in Table 2.

Table 2: Standardization of Polyherbal Churna.

Sr. No.	Parameter	Polyherbal Powder
1	PH	5.84
2	Total Ash Value	8.5%
3	Acid Insoluble Ash	7%
4	Water Insoluble Ash	23.5%
5	Water Soluble Extractive Value	3.90%
6	Ethanol Soluble Extractive Value	3.35%

7	Chloroform Soluble Extractive Value	4.10%
8	Moisture Content	0.32%
9	Swelling Index	Negative

3) Pre–Formulation Study

Physical properties for polyherbal churna.

Table 4: Physical Evaluation.

Physical Parameter	Value
Bulk Density	0.34g/ml
Tapped Density	0.52g/ml
Angle of Repose	33°19
Carr's Index	30
Hausner's Ratio	0.7

4) In-Vitro Characterization: It includes

4.1) Standardization of Polyherbal Churna like determination of pH, total ash, acid insoluble ash value, water soluble extractive value, acid insoluble ash value, water insoluble ash value, water soluble extractive value, ethanol soluble extractive value, chloroform soluble extractive value, moisture content and swelling index.

4.2) Evaluation parameters such as bulk density, tapped density, angle of repose, Carr's Index, Hausner's ratio.

EXPECTED OUTCOME

From this study it could be hypothesis that, we can prepare and formulate a stable polyherbal churna as an antacid as well as laxative. Which have no any side effects or adverse effects as compared with allopathic drugs or existing formulations. We could prepare non habitual laxative dosage form by taking ayurvedic (herbal) ingredients.

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