



FORMULATION AND EVALUATION OF KAYAM CHURNA WITH ITS DOSAGE FORMS

***DR. SHAIKH MUZAFFAR AHMED¹ | DR. GHUFRAN AHMAD QAMRUDDEEN² | DR. ANSARI SUMAIRA ABDUL SALAM³ | PROF. IRFAN AHMAD⁴ | PATHAN NAYEEM⁵ | SHAHID PATHAN⁶ | ABID MANYAR⁷**

¹ PROF. & H.O.D, DEPARTMENT OF KULLIYAT, A.G. UNANI MEDICAL COLLEGE, AKKALKUWA, DIST:

NANDURBAR: 425415, M.S.

² ASSISTANT PROFESSOR, DEPARTMENT OF KULLIYAT, A.G. UNANI MEDICAL COLLEGE, AKKALKUWA, DIST:

NANDURBAR: 425415, M.S.

³ ASSISTANT PROFESSOR, DEPARTMENT OF ILMUL JARAHAT, A.G. UNANI MEDICAL COLLEGE, AKKALKUWA, DIST:

NANDURBAR: 425415, M.S.

⁴ STATE UNANI MEDICAL COLLEGE AND HOSPITAL, HIMMATGANJ, PRAYAGRAJ: 211001, U.P, INDIA.

⁵ DEPARTMENT OF QUALITY ASSURANCE, ALI ALLANA COLLEGE OF PHARMACY AKKALKUWA, KBC NMU UNIVERSITY, JALGAON, MAHARASHTRA-425002, INDIA.

⁶ LECTURER, SAMARTH INSTITUTE OF PHARMACY, SAKRI, DIST: DHULE-424304, M.S, INDIA.

⁷ DEPARTMENT OF PHARMACEUTICS, ALI ALLANA COLLEGE OF PHARMACY AKKALKUWA, KBC NMU UNIVERSITY, JALGAON, MAHARASHTRA-425002, INDIA.

ABSTRACT:

Kayam churna is a popular Ayurvedic preparation to relieve constipation. It is not a traditional Ayurvedic preparation. It is a proprietary Ayurvedic medicine. It means that the formula of Kayam churna is not mentioned in any Traditional Ayurvedic text books. The manufacturer of Kayam Churna, Sheth Brothers, formulated a combination of few Ayurvedic herbs that benefit in constipation, blended them into powder form and labeled it as Kayam churna. As the standardization of herbal formulation is great concern for its safety and efficacy for that reason this work is aimed to formulation comparative evaluation of kayam churna with marketed product.

KEYWORDS:

KAYAM CHURNA, HERBAL FORMULATION, MARKETED PRODUCT, STANDARDIZATION.

INTRODUCTION

Herbal medicines are one type of dietary supplement. They are sold as tablets, capsules, powders, teas, extracts, and fresh or dried plants. People use herbal medicines to try to maintain or improve their health. Many people believe that products labeled "natural" are always safe and good for them. This is not necessarily true. Herbal medicines do not have to go through the testing that drugs do. Some herbs, such as comfrey and ephedra, can cause serious harm. Some herbs can interact with prescription or over-the-counter medicines. If you are thinking about using an herbal medicine, first get information on it from reliable sources. Make sure to tell your health care provider about any herbal medicines you are taking. Products made from botanicals, or plants, which are used to treat diseases or to maintain health, are called herbal products, botanical products, or phytomedicines. Many prescription drugs and over-the-counter medicines are also made from plant products, but these products contain only purified ingredients and are regulated by the FDA. Herbal supplements may contain entire plants or plant parts. The FDA considers herbal supplements foods, not drugs. Therefore, they are not subject to the same testing,

manufacturing, and labeling standards and regulations as drugs. Herbal product cannot be considered scientifically valid if the drug tested has not been authenticated and characterized in order to ensure reproducibility in the manufacturing of the product. Standardization is a process that ensures a predefined amount of quantity, quality & therapeutic effect of ingredients in each dose. Moreover, many dangerous and lethal side effects have recently been reported, including direct toxic effects, allergic reactions, effects from contaminants, and interactions with herbal drugs. The development of authentic analytical methods which can reliably profile the phytochemical composition, including quantitative analyses of marker, bioactive compounds and other major constituents. In view of the above, standardization is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for production and manufacturing of an herbal drug.

Modern day awareness of the needs for Herbal Standardization and Evaluation have been aptly

summarized in the words of Drugs Controller of India, Mr. Ashwini Kumar: "In earlier days, the activity of herb procurement, preparation and dispensing remained mainly the responsibility of practitioners and was on a one to one relationship between physician and his patients. It was a matter of sacred trust. However, the socio-economic changes in modern times, the technological advances, commercial factors, consumer preferences, changing lifestyles, etc. has influenced the way Herbal drugs are being 'manufactured' and distributed in the country. The Practitioner as well as the Consumer now seek assurance from the manufacturer about quality, safety and efficacy of a readymade Herbal Supplement or Medication.^[4] As the standardization of herbal formulation is great concern for its safety and efficacy for that reason this work is aimed to standardization of herbal formulation (Kayam Churna).

Kayam churna is a popular Ayurvedic preparation to relieve constipation. It is not a traditional Ayurvedic preparation. It is a proprietary Ayurvedic medicine. It means that the formula of Kayam churna is not mentioned in any Traditional Ayurvedic text books. The manufacturer of Kayam Churna, Sheth Brothers, formulated a combination of few Ayurvedic herbs that benefit in constipation, blended them into powder form and labeled it as Kayam churna.^[5]

MATERIALS AND METHODS

PLANT MATERIAL COLLECTION

The all plant materials and marketed formulation of Kayam Churna were purchased from local market. The dried parts were coarsely powdered in grinder and powder materials was sieved through 60-120 mesh and subjected for preparation of a poly herbal churna (Kayam Churna).

PREPARATION OF KAYAM CHURNA

The Kayam Churna is prepared by simple mixing appropriate amount of plant material mention in marketed formulation. The quantity is given below in table no 1.^[5]

TABLE 1: FORMULATION TABLE.

Sr. No.	Name of Ingredients		Quantity %
	Ayurvedic	English	
1	Senna leaves	Cassia angustifolia	50
2	Kalanamak	Black Salt	18
3	Nishoth	Oerculina turpethum	10
4	Ajwain	Trachyspermum ammi	11.50
5	Haritaki	Terminalia chebula	7
6	Svarjika Kshara	Sod. bicarbonate	5
7	Yasthimadhu	Glycyrrhiza glabra.	4.50

ORGANOLEPTIC EVALUATION: Macroscopic study was carried out by means of sense organs. Which involve the

evaluation of drug the process included the observation of the colour, odour, taste of Prepared and marketed formulation of Kayam Churna such as color, odor, size and shape.^[6]

DETERMINATION OF WATER- SOLUBLE ASH

The ash, obtained as per the method described above boiled for 5 minutes with 25 ml of water, filtered, and collected the insoluble matter in a Gooch crucible, washed with hot water and ignited for 15 minutes at a temperature not exceeding 450°C and weight was taken. Subtracted the weight of the insoluble matter from the weight of the ash; the difference in weight represents the water-soluble ash. The percentage of water-soluble ash was calculated with reference to air-dried drug.^[7]

DETERMINATION OF ACID -INSOLUBLE ASH

The ash obtained as per method described above and boiled with 25 ml of 2 M hydrochloric acid for 5 minutes, filtered, and collected the insoluble matter in a Gooch crucible or on an ash less filter paper, washed with hot water, ignited, and cooled in a desiccator and weighed. The percentage of acid-insoluble ash was calculated with reference to the air-dried drug.^[7]

DETERMINATION OF LOSS ON DRYING

Accurately weighed glass Stoppard, shallow weighing bottle was dried and 2g of sample (Prepared and marketed formulation) was transferred to the bottle and covered, the weight was taken and sample was distributed evenly and poured to a depth not exceeding 10 mm. Then loaded bottle was kept in oven and stopper was removed. The sample was dried to constant weight. After drying it was collected to room temperature in a desiccator. Weighed and calculated loss on drying in terms of percent w/w .^[7]

DETERMINATION OF TOTAL ASH

Accurately weighed 2g of the air-dried sample (Prepared and marketed formulation) was taken in a tared silica dish and incinerated at a temperature not exceeding 450°C until free from carbon, cooled in a desiccator and weight was taken. The process was repeated till constant weight was obtained. The percentage of ash was calculated with reference to air-dried drug.^[7]

DETERMINATION OF SULPHATED ASH

Silica crucible was heated to redness for 10 minutes and allowed to cool in desiccator and weighed. 1 gm of air-dried sample (Prepared and marketed formulation) was weighed and ignited gently until the substance was charred cool. The residue was moistened with 1 ml sulphuric acid. It was heated gently until the white fumes no longer evolved and ignited at 800°C \square 25°C until all black particles had disappeared. Ignition was conducted in place protected from air currents. Crucible was cooled and few drops of sulphuric acid were added and ignited. Then it was allowed to cool and weighed.^[7]

DETERMINATION OF BULK DENSITY AND TAP DENSITY

The term bulk density refers to packing of particles or granules. The equation for determining bulk density (D_b) is $D_b = M/V_b$ where M is the mass of particles and V_b the total volume of packing. The volume of packing can be determined in an apparatus consisting of graduated cylinder mounted on mechanical tapping device that has a specially cut rotating can. Hundred grams of weighed formulation powder was taken and carefully added to cylinder with the aid of a funnel. The initial volume was noted and sample was then tapped until no further reduction in volume was noted. The initial volume gave the bulk density value and after tapping the volume reduced, it gives the value of tapped density.^[8]

PRELIMINARY PHYTOCHEMICAL SCREENING

The sample (Prepared and marketed formulation) were then subjected to preliminary phytochemical screening to detect the presence of various phytoconstituent.^[6,9-11]

DETERMINATION OF EXTRACTIVE VALUE

Different extractive values like alcohol soluble extractive, water soluble extractive values were performed by standard method.^[7] 5 gm of air dried sample (Prepared and marketed formulation) was macerated with 100 ml of chloroform water in a closed flask for 24 hours, and it was shaken frequently during first 6 hours and allowed to stand for 18 hours. Then it was filtered, 25 ml of the filtrate was evaporated in a flat shallow dish, and dried at 105°C and weighed. Percentage of water-soluble extractive value was calculated with reference to air-dried drugs.

For determination of alcohol soluble extractive, chloroform soluble extractive values and petroleum ether soluble extractive value only solvent was changes and the above procedure repeated.

RESULTS AND DISCUSSION

ORGANOLEPTIC EVALUATION

Marketed formulation have fine particle size, Greenish brown color, with salty taste and characteristics odor while prepared formulation have dark brown color, characteristics odor with salty taste and have fine particle size.

TABLE 2: ORGANOLEPTIC CHARACTERISTICS OF FORMULATIONS.

Morphological Characteristics	Observation	
	Marketed Formulation	Prepared Formulation
Color	Greenish brown	Dark brown
Odor	Characteristics	Characteristics
Taste	Salty	Salty

DETERMINATION OF LOSS ON DRYING

The percentage of loss on drying of Marketed Formulation and prepared formulation were found to be 10.50 and 11.0%w/w respectively.

TABLE 3: LOSS ON DRYING OF FORMULATIONS.

Parameter	Loss on drying (%w/w)	
	Marketed Formulation	Prepared Formulation
Loss on drying	10.80	11.50

DETERMINATION OF ASH VALUE

Marketed formulation have total ash, water- soluble ash acid insoluble ash and sulphated ash. 17.40, 7.38, 4.29 and 22.28% w/w respectively, while prepared formulation have total ash, water- soluble ash, acid insoluble ash and sulphated ash. 15.90, 7.10, 3.32 and 21.20% w/w respectively.

TABLE 4: ASH VALUE OF FORMULATIONS

Sr. No.	Parameters	Values (% W/W)	
		Marketed Formulation	Prepared Formulation
1	Total ash	17.40	15.90
2	Water- soluble ash	7.38	7.1
3	Acid insoluble ash	4.29	3.32
4	Sulphated ash	22.28	21.20

DETERMINATION OF EXTRACTIVE VALUE

Marketed formulation have petroleum ether, chloroform, alcohol and water soluble extractive value 8.10, 9.60, 17.85 and 37% w/w respectively, while prepared formulation have petroleum ether, chloroform, alcohol and water soluble extractive value 4.90, 6.23, 12.08 and 47 % w/w respectively.

TABLE 5: EXTRACTIVE VALUES OF THE FORMULATIONS WITH DIFFERENT SOLVENTS.

Sr.No.	Extractive	Extractive value (%w/w)	
		Marketed Formulation	Prepared Formulation
01	Petroleum Ether	8.10	4.90
02	Chloroform	9.6	6.23
03	Alcohol soluble	17.85	12.08
04	Water soluble	37	47

PRELIMINARY PHYTOCHEMICAL SCREENING

Preliminary Phytochemical tests were performed for Carbohydrate, Protein, Amino acid, Steroids, Glycosides, Alkaloids, Flavonoids and Tannins. Preliminary Phytochemical tests showed the presence of all the phytochemicals analysed in both formulation, except steroids.

TABLE 6: PRELIMINARY PHYTOCHEMICAL SCREENING OF FORMULATIONS.

Sr.no.	Chemical test	Marketed Formulaion	Prepared Formulation
	Test for Carbohydrates		
1.	a) Molisch Test	+	+
	b) Fehilings Test	+	+
	c) Benedicts Test	+	-
	d) Barfoed's Test	+	-
	Test for Proteins		
2.	a) Biuret Test	-	+
	b) Millions Test	+	+
	c) Xanthoprotien Test	-	-
	Test for Amino Acids		
3.	a) Ninhydrin Test	+	+
	Test for Steroids		
4.	a) Salkowski Test	-	-
	b) Liebermann - Burchard reaction	-	-
	c) Liebermann's reaction.	-	-
	Test for Glycosides		
5.	a) Deoxysugares (Killer-Killani Test)	-	-
	b) Legal's Test	+	+
	c) Brontrager's Test	-	+
	d) Modified Brontrager's Test	+	-
	e) Foam test	+	-
	Test for Alkaloids		
6.	a) Drogendroff's Test	+	-
	b) Mayers Test	+	+
	c) Hagers Test	+	+
	d) Wagners Test	+	-

	Test for Flavonoids		
7.	a) Lead Acetate	+	+
	b) Sodium Hydroxide	+	+
	c) Ferric Chloride Test	+	-
	Test for Tannins		
8	a) 5% Ferric Chloride Test	+	+
	b) Lead Acetate Test	+	+
	c) Dilute Iodine Test.	-	+
	d) Dilute Nitric acid Test.	+	+
	e) Potassium Permanganate Solution	+	+

CONCLUSION

The present study explain about different phytochemical as well as physicochemical features of Kayam Churna , an important poly herbal formulation. The present research gives significant data which will beneficial in standardization of formulation. From the findings, it is clear that both formulation having significant similarity in their phytochemical and physicochemical properties. Further work (HPLC/ HPTLC) is required to identify its quantitative standardization parameter or bioactive compounds.

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