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Standardisation of Avipattikar Churna- A Polyherbal Formulation

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ABSTRACT

Standardisation of herbal formulation is essential in order to assess the quality of drugs, based on the concentration of their active principles. The present paper reports on standardisation of Avipattikar churna, a poly herbal ayurvedic medicine used as remedy for acidity and complications associated with it like headache, nausea and vomiting. It is also used as laxative and helps to increase appetite. Avipattikar churna was prepared as per Ayurvedic Formulary of India. In-house preparation and two marketed have been standardised on the basis of organoleptic characters, physical characteristics and physico-chemical properties. The set parameters were found to be sufficient to evaluate the churna and can be used as reference standards for the quality control/quality assurance laboratory of a Pharmaceutical house.

Keywords: *Avipattikar churna, physicochemical parameters, polyherbal formulation, standardisation.*

INTRODUCTION

Standardisation is an essential factor for polyherbal formulation in order to assess the quality of drugs based on the concentration of their active principle. It is very important to establish a system of standardisation for every plant medicine in the market, since the scope of variation in different batches of medicine is enormous. Plant material when used in bulk quantity may vary in its chemical content and therefore, in its therapeutic effect according to different batches of collection e.g. collection in different season and/or collection from sites with different environmental surrounding or geographical location. The increasing demand of the population and chronic shortage of authentic raw materials have made it incumbent, so there should be some sort of uniformity in the manufacture of Ayurvedic medicines so as to ensure quality control and quality assurance (1). The World Health Organisation (WHO) has appreciated the

importance of medicinal plants for public health care in developing nations and has evolved guidelines to support the member states in their efforts to formulate national policies on traditional medicine and to study their potential usefulness including evaluation, safety and efficacy (1). “Avipattikar churna” is a polyherbal Ayurvedic medicine used as remedy for hyperacidity, indigestion, anorexia, urinary retention, constipation and piles (2). It is also used as laxative and helps to increase appetite. The present paper reports on the standardisation of Avapattikar churna based on organoleptic characters, physical characteristics and physico-chemical properties.

MATERIALS AND METHODS

Plant material –

Avipattikar churna consists of fourteen ingredients viz., *Zingiber officinale*, *Piper nigrum*, *Piper longum*, *Terminalia chebula*,

Terminalia bellirica, *Embelica officinalis*, *Cyperus rotundus*, salt (vida lavana), *Embelia ribes*, *Elettaria cardamomum*, *Cinnamomum tamala*, *Syzygium aromaticum*, *Operculina turpethum*, and *Saccharum officinarum* (3). All these ingredients were procured from the local market of Udupi, Karnataka, India and were authenticated by botanist V. Aravinda Hebbar, Professor and Head of the department of botany, M.G.M College, Udupi, Karnataka. A voucher specimen of the same has been deposited in the museum of Department of Pharmacognosy, Manipal College of Pharmaceutical Sciences, Manipal for future reference.

Preparation of Avipattikar churna –

The churna was prepared as per the procedure given in Ayurvedic Formulary of India. All the ingredients viz., *Zingiber officinale*, *Piper nigrum*, *Piper longum*, *Terminalia chebula*, *Terminalia bellirica*, *Embelica officinalis*, *Cyperus rotundus*, salt (vida lavana), *Embelia ribes*, *Elettaria cardamomum*, *Cinnamomum tamala*, *Syzygium aromaticum*, *Operculina turpethum*, and *Saccharum officinarum* were powdered separately, passed through 80 # sieve and then mixed together in specified proportions to get uniformly blended churna.

Marketed samples –

The marketed samples of various brands of Avipattikar churna i.e. Baidyanath (B) and Dabur (D) and the In-house preparation (I) were standardised based their organoleptic characters, physical characteristics and physico-chemical properties.

Organoleptic evaluation –

Organoleptic evaluation refers to evaluation of formulation by color, odour, taste, texture etc. The organoleptic characters (4) of the samples were carried out based on the method as described by Siddiqui et.al.

Physico-chemical investigations –

Physico-chemical investigations of formulations were carried out including determination of extractive values and ash values (5, 1).

Fluorescence analysis (4) –

The powdered samples were exposed to Ultraviolet light at wavelength of 254 nm and 366 nm. Fluorescence analysis was carried out in accordance with the procedure reported by Kokoshi et al. One mg of powdered drug was placed on a micro slide and observed under UV 366, UV 254 and in day light to observe the fluorescent characteristics of powder, if any. One mg powdered drug was placed on a

micro slide and treated with one ml 1N HCl and observed under UV 366, UV 254 and in day light while wet. One mg powdered drug was placed on a micro slide and treated with one ml 1N NaOH and observed after a few minute in day light, under UV 366, UV 254. One mg powdered drug was placed on a micro slide and treated with one ml 1N NaOH in one ml methanol and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml 50% KOH and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml of 50% sulphuric acid and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml of Conc. sulphuric acid and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml of 50% HNO₃ and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml of Conc. HNO₃ and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml of acetic and observed under UV 366, UV 254 and in day light while still wet. One mg powdered drug was placed on a micro slide and treated with one ml of iodine and observed under UV 366, UV 254 and in day light while still wet.

Determination of pH –

The pH of different formulations in 1% w/v and 10% w/v of water soluble portions were determined using pH paper (range 3.5–6) and (6.5–1.4) with standard glass electrode at 24° C.

Estimation of sodium content (6, 7) –

Sodium content was estimated by using a flame photometer.

This was done as as follow-

A stock solution 100µg/ml of NaCl was prepared in distilled water and further dilutions were made to get 1µg/ml, 2µg/ml, 3µg/ml, 4µg/ml, 5µg/ml, 10µg/ml respectively for preparing the standard graph shown in the table. Sodium content of the formulations was estimated by flame photometric method based on the measurement of emission intensity in nanometer. The method was validated for linearity, precision, and accuracy. The method obeyed Beer's law in the concentration range 1–10µl/ml. When a standard drug solution as assayed repeatedly (n=6), the mean error and relative standard deviation (precision).

Determination of physical characteristics of powder formulation (8, 9) –

Physical characteristics like bulk density, tap density, angle of repose, Hausner ratio and Carr's index were determined for different formulations. The term bulk density refers to method used to indicate a 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 is the total volume of packing. The volume of packing can be determined in an apparatus consisting of graduated cylinder mounted on mechanical tapping device (Jolting Volumeter) that has a specially cut rotating can. Hundred gm 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, giving the value of tapped density.

Angle of repose has been used as an indirect method quantifying powder flowability, because of its relationship with interparticle cohesion. The fixed funnel and the free standing cone method employs a method that is secured with its tip at a given height (H), above the glass paper that is placed on a flat horizontal surface. Powder or granules were carefully poured through the funnel until the apex of the conical pile just touched the tip of funnel. Thus, with R being the radius of the conical pile. $\tan \alpha = H/R$ or $\alpha = \arctan H/R$, where α is the angle of repose.

Hausner ratio is related to interparticle friction and as such can be used to predict the powder flow properties. The equation for measuring the Hausner ratio is D_t/D_o .

Where, D_t = Tapped density and D_o = Bulk density.

Carr's index is another indirect method of measuring the powder flow from bulk density. The equation for measuring Carr's index is

Where D_t = tapped density, D_o = Bulk density.

RESULTS AND DISCUSSION

In house formulation was prepared in accordance with the Ayurvedic Formulary of India (3). Water soluble and

alcohol soluble extractive values are given in the table 2 and ash values (total ash and acid insoluble ash) in table 1. The ash (1) values of the samples were carried out based on the method as described by the World Health Organisation (WHO) guidelines for medicinal plant materials. The physico-chemical and organoleptic comparisons between in-house formulations and marketed formulations are given in the table 3 and table 4 respectively. The results obtained with the market formulations and the in-house formulations were found to be comparable and variation

Table 1: % Ash values of individual ingredients present in Avipattikar churna (w/w)

Samples	Total ash Mean (n=3)± SD	Acid insoluble ash Mean (n=3)± SD
<i>Zingiber Officinale</i>	5.689 ± 0.072	0.643 ± 0.025
<i>Piper nigrum</i>	4.696 ± 0.602	0.330 ± 0.074
<i>Piper longum</i>	4.842 ± 0.396	0.473 ± 0.075
<i>Terminalia chebula</i>	2.778 ± 0.414	0.115 ± 0.028
<i>Terminalia bellirica</i>	4.218 ± 0.452	0.294 ± 0.093
<i>Embelica officinalis</i>	4.178 ± 0.637	0.381 ± 0.329
<i>Cyperus rotundus</i>	3.643 ± 0.217	3.595 ± 0.136
<i>Embelia ribes</i>	4.738 ± 0.702	0.194 ± 0.052
<i>Elletaria cardamomum</i>	2.626 ± 0.232	2.991 ± 0.201
<i>Cinnamomum tamala</i>	3.505 ± 0.271	0.210 ± 0.179
<i>Syzgium aromaticum</i>	3.624 ± 0.658	0.635 ± 0.089
<i>Operculina terpepethum</i>	4.147 ± 0.101	0.394 ± 0.184
<i>Saccharum officinarum</i>	0.199 ± 0.099	0.398 ± 0.050

Table 2: Extractive values of individual ingredients present in Avipattikar churna

Samples	Alcohol soluble (%) Mean (n=3)± SD	Water soluble (%) Mean (n=3)± SD
<i>Zingiber Officinale</i>	7.871 ± 0.577	27.47 ± 0.331
<i>Piper nigrum</i>	20.136 ± 0.304	11.502 ± 0.255
<i>Piper longum</i>	14.226 ± 0.518	14.931 ± 0.433
<i>Terminalia chebula</i>	98.714 ± 0.648	98.230 ± 0.340
<i>Terminalia bellirica</i>	69.726 ± 1.395	39.609 ± 0.304
<i>Embelica officinalis</i>	51.630 ± 0.417	77.256 ± 0.329
<i>Cyperus rotundus</i>	17.395 ± 0.406	26.221 ± 0.376
<i>Embelia ribes</i>	15.972 ± 0.401	10.418 ± 0.700
<i>Elletaria cardamomum</i>	20.846 ± 0.256	11.549 ± 0.549
<i>Cinnamomum tamala</i>	26.0 ± 0.518	20.534 ± 0.461
<i>Syzgium aromaticum</i>	31.579 ± 0.527	41.485 ± 0.546
<i>Operculina terpepethum</i>	17.209 ± 0.314	13.972 ± 0.364
<i>Saccharum officinarum</i>	28.359 ± 0.497	167.883 ± 0.589

Table 3: Physico-chemical characteristics of Avipattikar churna formulations

Parameter	In-house formulation Mean (n=3) ± SD	Baidyanath Mean(n=3)± SD	Dabur Mean(n=3)± SD
Water soluble extractive	58.246 ± 0.066	56.941 ± 0.223	53.814 ± 0.372
Alcohol soluble extractive	19.590 ± 0.36	17.026 ± 0.20	15.979 ± 0.172
Total ash values	2.952 ± 0.245	3.327 ± 0.077	3.557 ± 0.139
Acid insoluble ash	0.356 ± 0.073	0.931 ± 0.160	1.197 ± 0.098
pH of 1% w/v formulation solution	5.09 ± 0.036	4.806 ± 0.015	4.853 ± 0.005
pH of 10% w/v formulation solution	4.983 ± 0.102	4.556 ± 0.005	4.556 ± 0.005

Table 4: Organoleptic properties of different Avipattikar churna formulations

Formulations	Appearance	Colour	Taste	Odour
In-house	Powder	Light brown	Sweet	Characteristic
Baidyanath	Powder	Light brown	Sweet	Characteristic
Dabur	Powder	Buff color	Sweet	Characteristic

Table 5: Physical characteristics of different Avipattikar churna formulations

Parameters	In-house formulation Mean (n=3) ± SD	Dabur Mean (n=3) ± SD	Baidyanath Mean (n=3) ± SD
Tap density	0.504 ± 0.004	0.477 ± 0.009	0.555 ± 0.009
Bulk density	0.447 ± 0.002	0.417 ± 0.007	0.487 ± 0.004
Angle of repose	38.836 ± 0.887	41.015 ± 0.398	38.460 ± 0.893
Haussner ratio	1.129 ± 0.005	1.143 ± 0.003	1.142 ± 0.007
Carr's Index	11.432 ± 0.443	12.533 ± 0.222	12.447 ± 0.577

Table 6: Standard graph of sodium by flame photometry method

Concentration (mEq)	Emission Intensity (mV)
1.0	5.7
2.0	10.1
3.0	15.3
4.0	21.1
5.0	25.4
6.0	49.9

Table 7: Sodium content in different Avipattikar churna formulations

Different formulations	Sodium content (%)
In-house	9.8
Baidyanath	12.7
Dabur	7.2

Table 8: Powder fluorescence test of different Avipattikar churna formulations

Material	In-House		Baidyanath		Dabur	
	UV 254 nm	UV 366 nm	UV 254 nm	UV 366 nm	UV 254 nm	UV 366 nm
Powder as such	DB.	LB.	DB.	LB.	DB.	LB.
In NaOH(1N) in water	DB.	GF.	LB.	GF.	DB.	GF.
P + In HCl (1N)	DB.	GF.	DB.	Y.	DB.	GF.
P + in NaOH	DB.	GF.	LB.	GF.	DB.	GF.
(1N) in MeOH	DB.	GF.	LB.	GF.	DB.	GF.
P + 50 % KOH	DB.	GF.	DB.	GF.	DB.	GF.
P + 50 % H ₂ SO ₄	Y.	GF.	Y.	GF.	Y.	GF.
P + 50 % HNO ₃	B	GF.	B.	GF.	B.	GF.
P + conc. HNO ₃	B	GF.	B.	GF.	B.	GF.
P + CH ₃ COOH	Y.	Y.	LB.	Y	LB.	Y.
P + conc. H ₂ SO ₄	DB.	GF.	DB.	GF.	DB.	GF.
P + Iodine in water	B.	GF.	B.	GF.	DB.	GF.

P: Powder, Y: yellow, DB: Dark brown, GF: Green fluorescence, B: Black, LB: Light brown.

was insignificant. Acid insoluble ash value for in-house formulation was found to be 0.356 ± 0.073 (Average value along with standard deviation), in case of marketed formulation this was found to be 0.931 ± 0.160 and 1.197 ± 0.098 (Baidyanath and Dabur sample respectively). The pH from 1% w/v and 10% w/v solution revealed that pH of all the three formulations were comparable and was slightly acidic for all the formulations (i.e. in-house, Baidyanath and Dabur). The various physical characteristics have been presented in Table 5.

Estimation of sodium content shows that the sodium content in various formulations were also comparable. The standard plot for sodium content is given in table 6 and the sodium content was found to be highest in Baidyanath formulation compared to in-house and Dabur formulations (average value along with standard deviation) (n=3) are shown in table 7. In Table 8 fluorescent analysis of different Avipattikar churna formulations have been reported.

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