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Comparative Physico Chemical Analysis of Bilwadi Agada: An Ayurvedic Poly-Herbal Formulation W.S.R to Market Sample

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Abstract

Background: The quality control assessment of Poly- herbal formulations is of great significance in order to justify their acceptability in modern system of medicine though the drug may be therapeutically potent. Ayurveda and its rapidly increasing use by public has given rise to many newer issues and challenges. Ayurvedic formulations prepared by several manufactures are guaranteed to carry out the quality control test as per preliminary guidelines given by CCRAS (Central Council of Research in Ayurveda & Siddha). Though the standards are followed, still the variability in their results has been observed when compared between same formulations. Bilwadi Agada is one such Poly- herbal formulation consisting of 13 drugs & treated in Garavisha & Jangama visha etc. The condition which produces ailments like Pandu, Krusha, Alpaghni, Kasa, swasa, Aridta ,when triggering factor are congregate.

An attempt is made here to compare Bilwadi Agada prepared by GMP certified pharmacy within house preparation. Results revealed that the both the samples differ in their organoleptics, pH & Physico- chemical properties, Thin layered chromatographic study showed ,major difference was seen in disintegration time & hardness of sample A i.e., hardness is 7.1 but none of them disintegrates in 35min, whereas sample B hardness is 4.2, but disintegrates in 15min. The physic chemical data of this comparative study assists in maintaining the standard limits of Bilwadi Agada.

Keywords: Bilwadi Agada; Garavisha; Poly-Herbal Formulation; Physico-Chemical Analysis; TLC.

Introduction

Ayurveda the ancient spiritual science & Indian system of medicine in the present scenario has gained popularity & also increased inclination towards herbal formulations globally due to its effective & efficacious results witnessed in various diseases & syndromes in the recent epic. Herbal drugs are the core of this system of medicine as the drug possess all the required quality to prevent & cure various ailments.

The principles to standardize the drugs that were developed in ancient period were subjective & are based on the scientific background prevailing in those days .Now they are to be viewed & answered looking the advancement of science & technology in current days. Hence there is very much need to validate Ayurvedic formulations with the aid of sophisticated instrumental & analytical techniques.

The need of quality control for Ayurvedic formulations is due to reduction in the procedure of preparing drugs by ancient method due to commercialization of Ayurvedic pharmacy in present era [1]. These manufactures though prepare similar formulation fails to meet the standard quality control parameters when compared .

Bilwadi Agada is one such Poly- herbal formulation explained in the context of Garavisha in Ayurvedic classics which is a combination of 13 drugs & it has efficacy over a condition where in a visha (toxins) due to improper elimination from body or when low potent toxins by virtue or which are battered by climatic conditions stays in body, later produces when Pandu, Krusha, Alpaghni, Kasa, swasa, Aridta, triggering factors are congregate [2].

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Materials and Methods

Pharmaceutical Part (Raw Material Procurement)

Market Sample: Two samples of Bilwadi Agada one is in house prepared & another is manufactured by GMP certified pharmacy collected from the Belgaum market and given the code as BA(a) & BA(b) respectively.

Method of Preparation [3]

In House Sample Preparation

Bilwadi Agada consists of 13 ingredients of which 13 are herbal only. All the drugs of Bilwadi Agada were procured from market dealer and were authenticated at AYUSH approved Central Research Laboratory of KLE University's Shri B.M. Kankanwadi Ayurved Mahavidhyalaya Belgaum, Karnataka, India. Solvents and chemicals of analytical grade were procured from E. Merck and S.D. fine chemicals, Mumbai for analysis of Bilwadi Agada.

Table 1: Ingredients of bilwadi agada are as follows

S. No	Drug Name	Latin name	Used part	Quantity
01	Bilwa	*Aegle marmalos* corr ex Roxb	Mula (Root)	1Part
02	Surasa	*Ocimum santum* Linn	Puspha (Inflorosence)	1Part
03	Karanja	*Pongamia pinnata* Linn	Beeja (Seeds)	1Part
04	Nata	*Valerinia wallichi* DC	Kanda (Rhizome)	1Part
05	Devadaru	*Cedrus deodaru* Roxb	Saara (Heartwood)	1Part
06	Haritaki	*Terminalia chebula* Retz	Phala (Fruit)	1Part
07	Bibhitaki	*Terminalia belerica* Roxb	Phala (Fruit)	1Part
08	Amalaki	*Emblica officinalis* Gaertn	Phala (Fruit)	1Part
09	Shunti	*Zingibera officinale* Rose	Kanda (Rhizome)	1Part
10	Maricha	*Piper nigrum* Linn	Phala (Fruit)	1Part
11	Pippali	*Piper longum* Linn	Phala (Fruit)	1Part
12	Haridra	*Curcuma longa* Linn	Kanda (Rhizome)	1Part
13	Daruharidra	*Berberis aristata* DC	Twak (Stem bark)	1Part
14	Ajamutra	Goat urine	Urine	Q.S

Table 2: Showing the organoleptic characters of *bilwadi agada*

Sr. No.	Parameters	*BA(a)*	*BA(b)*
1	Colour	Brownish black	Light Green
2	Odour	Ajamutra Gandhi	Nil
3	Taste	Pungent, Bitter	Punget, Bitter
4	Consistency	Hard	Soft

Table 3: Showing the physicochemical properties of *bilwadi agada*

Sr. No.	Parameters	*Bilwadi Agada(a)*	*Bilwadi Agada(b)*
1	pH at 5% aqueous solution	8.4	7.8
2	Loss on Drying at 110^0C (% w/w)	12%	10.2%
3	Total Ash (% w/w)	20.7%	15.6%
4	Acid Insoluble Ash (% w/w)	2.415%	0.925%
5	Water Soluble Ash (% w/w)	4.16%	2.24%
6	Water Soluble Extractive (%w/w)	15.4%	11.45%
7	Alcohol Soluble Extractive (%w/w)	7%	5%

Table 4: Showing the inorganic test of *bilwadi agada*

Sr. No.	Parameters	*Bilwadi Agada(a)*	*Bilwadi Agada(b)*
1	Calcium	Present	Absent
2	Magnesium	Present	Absent
3	Sodium	Present	Absent
4	Potassium	Absent	Absent
5	Iron	Present	Present
6	Sulphate	Present	Present
7	Chloride	Present	Present
8	Carbonate	Absent	Absent
9	Nitrate	Absent	Absent

Table 5: Showing the organic test of *bilwadi agada*

Sr. No.	Parameters	Test	*Bilwadi Agada* (a)Ext.		*Bilwadi Agada* (b)Ext.	
			Aq	A/L	Aq	A/L
1	Carbohydrates	Molish	+	+	+	+
2	Reducing Sugar	Benedict's	+	+	+	+
3	Monosaccharides	Barfoed's	-	-	-	-
4	Non reducing sugar	Benedict's	-	-	-	-
5	Pentox sugar	Bial's	-	-	-	-
6	Hexose sugar	Selwinoff's	+	+	+	+
7	Proteins	Million's	+	+	+	+
8	Amino Acids	Cysteine	+	+	+	+
		Tyrosine	+	-	+	-
9	Steroids		+	+	+	+
10	Glycosides	Cardiac Glycosides	-	-	-	-
11	Flavonoids		+	-	+	-
12	Alkaloids	Dragandroff's	+	+	+	+
13	Saponin		+	-	+	-
14	Fats & Oil	-	+	+	+	+

Table 6: Showing TLC- RI values of alcoholic extract of bilwadi agada with solvent system toluene: ethyl acetate (7:3)

Sl. No.	Condition	Rf values of *Bilwadi Agada(a)*	Rf values of *Bilwadi Agada(b)*
1.	Short wave (Spots at UV 254nm)	0.05,0.98,0.22,0.27,0.37, 0.45,0.57,0.66,0.71	0.03, 0.1, 0.15, 0.18, 0.4, 0.47, 0.6, 0.68
2.	Long wave (Spots at UV 366nm)	0.10,0.14,0.20,0.24,0.28,0.32, 0.37,0.41,0.55,0.59,0.70	0.03,0.8, 0.13, 0.18, 0.212, 0.25, 0.27, 0.31, 0.36, 0.4 0.42, 0.55, 0.61, 0.78

Table 7: Showing the results of microbial limit test of *bilwadi agada*

Sr. No.	Pathogens	Limits (As per IP)	Results *Bilwadi Agada*
1	E coli	Absent	Absent
2	S aureus	Absent	Absent
3	P aeruginose	Absent	Absent
4	S abony	Absent	Absent

Table 8: Showing the results of microbial load test of *bilwadi agada*

Sr. No	Description macroscopic	Limits (As per IP)	Results
1.	Total bacterial count	30-300cfu/ml	37cfu/ml
2.	Total fungal count	10-100cfu/ml	22cfu/ml

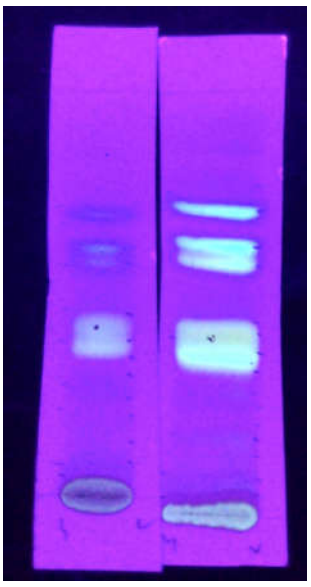

Fig. 1: TLC of Inhouse prepared BA(a) & Market sample BA

Instruments and Equipment's

Weighing machine, Analytical balance, Pulverizer, Clean cotton cloth, Steel vessel, Mask, Cap, Apron, Sieve no 85 and 120, Gas and stove.

Preparation of Churna

The *Churna* (powder) was prepared as per the procedure explained in Ayurvedic Formulary of India. All drugs were made into fine powder in a pulveriser. These *churna* are passed first through 85# mesh followed by 120 # sieve individually and then all are mixed together in equal proportions to get uniformly blended homogenous mixture.

Preparation of Bilwadi Agada

a. Authenticated drugs were pulverised to powder

& then sieved through 120 sieve mesh.

b. Daily fresh Ajamutra was collected & subjected to urine routine examination to confirm that, its free from pus cells, Micro-organisms, sugar, proteins etc contaminations at KLEU'S Shri B.M.K.Ayurveda Mahavidyalaya & Research center Laboratory Shahapur, Belagavi, Karnataka.

c. All the individual *choornas* (50gms each) were mixed with *Ajamutra* (Q.S) and bhavana was given. *Bhavana dravya* was mentioned in *Bilwadi Agada.*

d. Daily fresh *bhavana dravya* was taken in require quantity & *Mardana* was done till proper consistency was obtained (8hrs).

e. *8hrs Bhavana* was done daily for 22days at KLEU'S Shri.B.M.K. Ayurveda Mahavidyalaya& Research centre RS & BK Laboratory.

f. During the course of preparation of *Bilwadi Agada*-daily temperature & humidity were noted down. *& Mardana* time, colour, consistency, odour, taste of *Bilwadi Agada* were recorded in chart.

g. This procedure were followed for 22days (for more than 170hrs)

h. On 22nd day the vati were prepared & shade dried in stainless steel plate.

i. Then stored in dried sterilized glass container

j. Good manufacturing procedure followed throughout the preparation of *Bilwadi Agada.*

Analytical Part [4]

Analytical study was carried out in AYUSH approved Central Research Laboratory of Shri B.M.K. Ayurveda Mahavidyalaya Belgaum. Microbial Limit Test was carried out in Microbiology Laboratory of KLE University's Shri B.M. Kankanwadi Ayurveda Mahavidhyalaya Belgaum, Karnataka, India.

The Samples has been Analyzed for

1. Organoleptic Characters
2. Quantitative parameters
3. Microbial limit
4. Physicochemical Properties
5. Quatitative Properties
6. TLC

Results & Discussion

Physicochemical analysis of *Bilwadi Agada* of market sample and in house preparation has been carried out and the results are shown in tables. Ayurvedic formulations claimed to be made according to CCRAS guidelines are effective but it is very difficult to maintain uniformity in formulations which is may be due to natural heterogeneity, the quality of herbal starting material obtained from wild collection shows more and more fluctuations which can be depicted from our experimental data [5].

Analytical study was conducted at final product of Bilwadi Agada. Physicochemical analysis & preliminary phytochemical analysis of final product of Bilwadi Agada was done.

Organoleptic Study

Organoleptic of both samples reveals adequate differences observed in the presentation of the formulation and their taste i.e. sample (a) are handmade pills so they are round & brownish black in color and sample (b) are punched tablets indicates about addition of some binders and are light greenish in color.

Moisture Content

Moisture content in a drug is an important tool for a stability of any formulation. If moisture is high, it provides healthy environment for microbial growth. Sample (a) is having more moisture content than sample (b) i.e., 12% w/w & 2.926% w/w respectively.

Ash Value

Ash value represents amount of non-physiological components present in the drug [6]. Lesser the amount of ash, less the impurities Sample (a) has lesser ash value when compared to sample (b) i.e. 20.7%w/w and 4.39% w/w.

Extractive Values

Extractive value explains the amount of constituents that are extracted from a drug in a given solution. As the *Vati* is administered along with water as a common *anupana*, maximum extraction must be observed in aqueous extract. Both samples have shown high aqueous extractive value.

pH value

pH determines acidity or alkalinity of a drug. PH for sample (a) is 8.4 which is a bit alkalinity compared to the sample (b) had 7.8

Physical Characteristics for Tablets

The physical test for tablets i.e. Weight variation

test where 20 tablets are randomly selected and weighed. The mean and standard deviation was calculated. Here in this study sample (a) and (b) has shown significant difference in their weight. This might be due to the sample (a) pills prepared were handmade. The disintegration time and hardness of tablet are important tools for physical stability and absorption rate.

Both procedures must be directly proportional to each other. But in this study the hardness of sample (a) is 7.1 kg/cm3 but disintegration time is 35 min. Disintegration time should not be more than an hour, unless specified otherwise [7]. Whereas hardness of sample (b) is 4.2kg/cm3 and disintegration time is 15min. Disintegration test of both samples were done for 18 tablets. Such change affects the bioavailability of the drug to withstand in the body and show its efficacious results. But in this case as agadas were powdered & administered. So there is no much importance of hardness.

Phytochemical Analysis

Are done to know the presence of functional group, which play a vital role in expression of therapeutic efficacy. Both the samples showed presence of Carbohydrates, reducing sugars, glycosides, Fats & oils, steroids, alkaloids & saponines shown in Table 5.

Qualitative Analysis

TLC study is carried out on 60F 254 pre-coated TLC plates under the solvent system Toulene and Ethyle acetate in the ratio 7:3 after various trial and errors. Ethanol extracts of all the samples have been taken and visualized under UV light chamber at the range of 255nm and 365nm. This parameter gives idea about qualitative estimation presence of various components of drugs. Results of TLC are shown in table no.06.

Microbial Limit Test

Microbial limit test has been carried out for all the samples and study reveals all samples were within the limits as per Indian Pharmacopeia Standard.

Conclusion

Bilwadi agada a Poly-herbal formulation treated for the ailments Sarpa visha damsha, Lootavisha, Udduravisha, Vricchika visha, Visuchika, Ajeerna, Jwara,Ykrutvikaras, Pleehavikaras, which are seen in Garavisha condition. Being the same formulation prepared by various manufacturers yet there is difference observed when markets sample and in house preparation are compared through standard quality control parameters as per Ayurvedic Pharmacopeia of India. Hence it is the need of hour that the Ayurvedic formulations are to be standardized in order to make them potent and therapeutically efficient.

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