Research Article

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STANDARDIZATION AND QUALITY EVALUATION OF SELECTED SINGLE DRUG FORMULATIONS (CHOORNAS) FROM AN AYURVEDIC PHARMACY

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Received on: 04/05/14 Revised on: 23/07/14 Accepted on: 02/08/14

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DOI: 10.7897/2277-4343.05494

ABSTRACT
It is essential to maintain the quality of the Ayurvedic medicines at various levels from raw material selection to packaging. Present study reports the reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of analysis for standardization of drugs. Ayurvedic drugs prepared in Sri Jayendra Saraswathi Ayurveda Medical College and pharmacy were subjected for quality evaluation. Four commonly used single drug formulations *via*., bala (*Sida cordifolia*), yastimadhu (*Glycyrrhiza. glabra*), rasna, (*Alpinia galanga*) and ashwagandha (*Withania somnifera*) were selected as candidate drugs for the detailed pharmacognostic study. Selected drugs were subjected to basic physicochemical analysis and extractions were carried out in ethanol, methanol and water. The extracts were analysed for phytochemical constituents like, proteins, carbohydrates, phenols and tannins, flavonoids, saponins, glycosides, steroid, terpenoids and alkaloids. Major compounds in the crude extracts were separated using thin layer chromatography (TLC). The basic characteristics of the drug extracts could be correlated to the textual reference in Ayurvedic literature. The results of the study showed that the selected drugs meet the pharmacopoeial standards in most of the criteria. The outcome of the study suggests that routine practice of these quality control tests help to maintain the standards for effective therapeutic usage.
Keywords: Quality evaluation, single drug formulations, choornas.

INTRODUCTION

Ayurvedic medicinal plants are in high demand as effective therapeutic agents worldwide. More than 4000 formulation units manufacture various formulations of herbal drugs which are supplied for use in India and exported to many other countries. To maintain the quality and reliability of the drugs for the consumers the manufacturers need to maintain the minimum standards at various levels from raw material selection to packaging. Due to lack of infrastructures, skilled manpower, reliable methods and stringent regulatory laws most of these manufacturers do not follow the standard procedures and manufacture their product on arbitrary basis. In order to have a good coordination between the quality of raw materials, in process materials and the final products, it has become essential to develop reliable, specific and sensitive quality control methods using a combination of classical and modern instrumental method of analysis. Standardization is an essential measurement for ensuring the quality control of the herbal drugs. The word "Standardization" is used to describe all measures, which are taken during the manufacturing process and quality control leading to a reproducible quality. "Evaluation" of a drug means confirmation of its identity and determination of its quality and purity and detection of its nature of adulteration. In order to obtain quality herbal products, care should be taken right from the proper identification of plants, season and area of collection, extraction and purification process and rationalizing the combination; in case of formulations. The herbal formulation can be standardized schematically. To formulate the medicament using raw materials, collected from different localities; comparative chemical efficacy of different batches of formulation need to be observed. The preparations with better clinical efficacy need to be selected. The routine physical, chemical and pharmacological parameters should be checked for all the batches to select the final finished product and to validate the whole manufacturing process. Hence the present work was undertaken to evaluate and standardize the Ayurvedic drugs prepared in SJSAMC pharmacy to ensure the availability of reliable and standard quality drugs for therapeutic usage in the college hospital and supply outside.

MATERIALS AND METHODS

Collection of medicinal plants

Medicinal plant specimens for the present study were selected from Sri Jayendra Saraswathi Ayurveda College, Chennai, India. The specimens were identified by Dr. P. R. Swaminathan, Professor and Head, Department of Dravyaguna, Sri Jayendra Saraswathi Ayurveda College and Hospital, Chennai, Inida. The plant materials selected for current study were Bala (*Sida cordifolia*), Yastimadhu (*Glycyrrhiza. glabra*), Rasna (*Alpinia galanga*) and Ashwagandha (*Withania somnifera*) and specimen samples are stored in college herbarium (SJSACH/Detp.DG/her/2013-14/1-4).

Pharmacognostic study

Basic pharmacognostic studies like, moisture content, total ash, acid insoluble ash, water soluble ash were estimated for the selected samples. Extractive values of the drugs in ethanol, methanol and water was estimated by dissolving 5 g of powdered drug in to 100 ml of 90 % ethanol, 100 % methanol and distilled water respectively. Extraction was done by following cold maceration method in magnetic stirrer for a period of 24 h. The extract was filtered and 25 ml of extract was kept for drying in the hot air oven maintained the temperature of 50^0 C. The samples were weighed and extractive value was calculated for each drug. pH of the each extractive

value was calculated using pH strips. All the drug extracts were subjected to phytochemical analysis to detect the presence of proteins (Millon's test and Ninhydrin test), carbohydrates, (Fehling's test, Benedict's test, Molisch's test, Iodine test), phenols and tannins, flavonoids (Shinoda test, Alkaline reagent), saponins, glycosides (Liebermann's test, Salkowski's test, Keller-kilani test), steroid, terpenoids and alkaloids[1]. To separate compounds from crude extracts thin layer chromatography (TLC) was conducted by using standard procedure. Briefly, mixture of chloroform and methanol and toluene: ethyl acetate (1:1) in equal proportion was used as solvent (mobile phase). TLC plates were spotted with different extracts and allowed to dry and then placed inside the TLC chamber. After the solvent has moved to 3/4th of the plate, the plate was taken from the chamber and viewed under UV chamber for spots. Developed plates were visualized by dipping the plate in vanillin sulfuric acid (1 %) and by heating on 105°C when colour of the spot appeared. The relative position was calculated by using the formula:

R_f = distance travelled by solute ÷ distance travelled by solvent

RESULTS AND DISCUSSION

Table 1: Characteristics of plant materials of Bala, Yastimadhu, Rasna and Ashwagandha

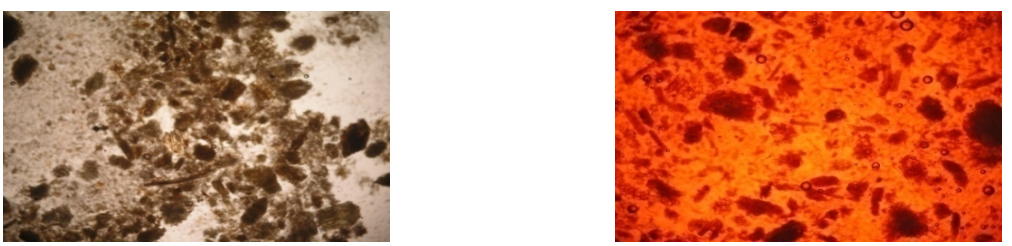
	Bala (*S. cordifolia*)	Yastimadhu (*G. glabra*)	Rasna (*A. galanga*)	Ashwagandha *(W. somnifera)*
Part used	Root	Root	Rhizome	Root
Colour of the powder	Greenish brown	Brownish yellow	Dark Brown	Yellowish brown
Taste	Bitter	Sweet/bitter	Bitter	Sweet
Quantitative macro-morphology		length - 2m, Diameter - 0.75-2.5 cm	Length - 5-10 cm Diameter - 3-5 mm	Length 10-20 cm Diameter – 0.6 – 1.25 cm
External features	Roots are thin, long, cylindrical, very rough and contorted	Highly branched, short taproot, grey brown exterior, yellow interior, longitudinal wrinkle with patches of cork	Cylindrical and slightly tortuous, Rough, fibrous surface, longitudinal wrinkles	long, tapering uniform, brittle short and starchy

Iodine stain (10x) **Safranin stain (10x)**

Figure 1: Stained powder microscopic structures of Bala Moola powder

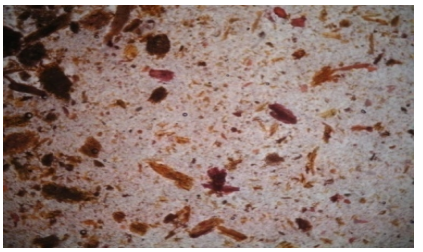
Unstained (10x) **Safranin stain (10x)**

Figure 2: Powder microscopy of yastimadhu powder showing cork cells, starch grains and prismatic crystals, fibres, bordered pitted vessels

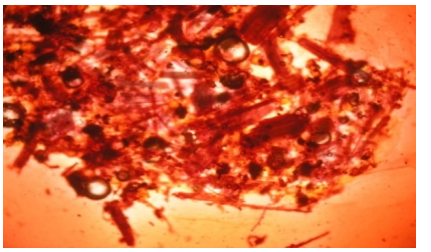


Unstained (10x) **Safranin stain (10x)**

Figure 3: Powder microscopy of rasna showing fragments of epidermal cells, Parenchymatous cells, oleoresin cells, elongated fibres with lignified and tapering ends



Iodine stain (10x)



Safranin stain (10x)

Figure 4: Starch grains, parenchyma cells prismatic crystals, tracheids, fibers with pitted vessels, spiral vessels, cork in surface view and tangentially elongated cork was
Iodine stain: Cortical parenchymatous cells embedded with simple and compound starch grains

Table 2: Percentage moisture, ash content of the experimental drugs

	Balamoola	Rasna	Yastimadhu	Ashwagandha
Moisture (%)				
Standard	NA	≤ 4.35	≤ 7	≤ 7-13
Present study	4.8 %	1.80	11.40	9.50
Total Ash (%)				
Standard	≤ 8.00	≤ 11.00	≤ 10.00	≤ 7.00
Present study	6.00	4.64	5.95	5.79
Acid insoluble ash (%)				
Standard	≤ 3%	≤ 1.00	≤ 2.50	≤1.58
Present study	6.5%	4.88	2.50	7.75
Water soluble ash (%)				
Standard	1.35	4.66	NA	NA
Present study	1.98	2.83	1.70	4.85
Aqueous extractive values (%)				
Standard	4.00	15.00	20.00	2.00
Present study	1.60	30.40	6.10	3.40
Ethanol extractive value (%)				
Standard	3.00	NA	NA	NA
Present study	0.80	4.00	4.40	1.00
Methanol extractive value (%)				
Standard	3.00	14.00	10.00	1.00
Present study	0.60	28.91	7.40	3.60

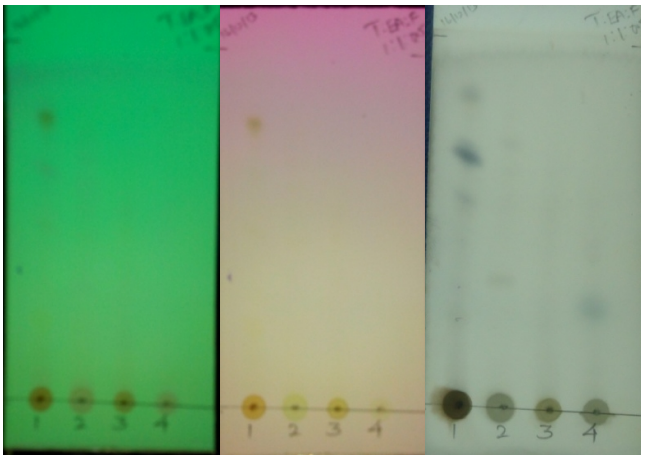
Table 3: Phytochemical analysis of rasna, balamoola, yastimadhu and ashwagandha

	Rasna			Balamoola			Yastimadhu			Ashwagandha		
Test for	Aq	Mt	Et	Aq	Mt	Et	Aq	Mt	Et	Aq	Mt	Et
Proteins	+	-	+	+	+	-	+	-	+	-	-	+
Carbohydrates	+	+	+	-	-	-	-	+	-	+	+	+
Phenols	+	+	+	+	+	-	+	+	+	-	-	-
Test for tannins	+	+	+	+	+	-	+	+	+	-	-	-
Flavonoids	+	-	-	+	+	-	+	-	-	-	-	-
Saponins	+	+	+	+	+	+	+	+	+	+	+	+
Terpenoids	-	_	-	-	_	-	-	_	+	-	_	+
Glycosides	+	+	+	+	+	-	-	-	+	+	+	+
Steroids	+	-	+	-	-	-	-	-	+	-	+	+
Alkaloids	-	-	-		-	-	+	+	+	+	+	+

Aq: Aqueous Mt: Methanol Et: Ethanol

Table 4: Rasa guna veerya and vipaka of the drugs

Drugs	Rasa	Guna	Vipaka	Veerya
Bala	Madhura	Guru	Madhura	Ushna
Rasna	Tikta	Guru	Katu	Usna
Ashwagandha	Madhura, Kashaya, Tikta	Laghu, Snigdha	Madhura	Usna
Yastimadhu	Madhura	Guru, Snighdha	Madhura	Sita[2,3]



UV 254 nm **UV 365 nm** **white light**

R_f Value: Track 1 (0.53, 0.67, 0.81), Track 2 (0.32, 0.73, 0.76), Track 3 (0.51, 0.62), Track 4 (0.31, 0.42, 0.52)

Figure 5: Thin layer chromatography pictures showing the R_f values for four drugs studied
R_f value calculated only white light TLC Plates

The result showed that yastimadhu contains more amount of moisture as compared to the standard and this may be due to lack of proper drying of the drug, moreover the drug contains more quantity of sugar this may also be one of the reason hence even after proper drying it get moistened so we need to take care of its packing. Ash value of the drug is an indicator of adulteration; however drugs tested in the present study showed no adulteration. Though the levels of acid insoluble ash were high and water soluble ash was recorded less than the standard further confirming the lack of any impurities in the tested drugs. Comparison of the extractive values with the prescribed standards showed that aqueous extract of rasna contains more extractive values indicating the therapeutic utility of aqueous preparations. However, in Ayurvedic text administration of the drug is mentioned in the form of kwatha kalpana (preparation of decoction in the water media), rasna panchaka, rasna saptaka and maharasnadhi kwatha etc. The observation in the present study suggests that active components of the rasna could be best obtained in kwatha kalpana preparations. In case of Ashwagandha, higher extractive values were observed both in aqueous extract and alcoholic extract suggesting the suitability of its use both as aqueous and alcoholic preparations. This is in accordance to the Ayurvedic text, where arista preparations were recommended for this drug and the main preparation is ashwagandharista. Yastimadhu and bala moola showed less extractive values in both aqueous and alcoholic media as compared to standards. The textual references have mentioned madura rasa, guru guna, madura vipaka, ushna veerya nature for bala which was confirmed in the present study by the presence of proteins, phenols, tannins, saponins and glycosoides. Tikta rasa, guru guna, ushna veerya and katu vipaka nature of rasna was also indicated by the presence of proteins, phenols, tannins, flavonoids, saponins and glycosides. Similarly, Madhura rasa, guru snigdha guna, sheeta veerya and madhura vipaka nature of yastimadhu showed the presence of proteins, carbohydrate, phenols, tannins, flavonoids, saponin and alkaloids and madhura rasa, guru snigdha guna, ushna veerya and madhura vipaka nature of ashwagandha showed the presence of proteins, carbohydrates, sapononis, glycosides and alkaloids. In general, presence of these phytoconstituents can be compared with the Ayurvedic parameters, like, madhura rasa by glycosides and carbohydrates, tikta rasa by alkaloids, kashya rasa presence of tannins and guru guna by proteins and usna veerya by pH of the drug as all the tested drugs showed pH 5 in aqueous media indicating the acidic nature of drugs. The result of the study suggests that macroscopic, microscopic, ash values, extractive values, phytochemical and TLC analysis of the samples are very essential for the authentication of the drug and quality control of raw drugs. The estimation of these parameters is highly essential for raw drugs or plant part used for the preparation of compound formulations. Hence, the periodic assessment is essential for quality assurance and safer use of herbal drugs.

REFERENCES

1. Trease GE and Evans WC. Pharmacognosy. 12th Edition. Published by Bailliere Tindall, London; 1983.
2. Bhava Prakasha Nighantu, Indian Materia Medica, Bhavamisra, commentary by KC Chunekar Ed. GS Pandey, Choukhambha Bharati Academy, Varanasi 10th Ed; 1995.
3. Sharm PV. Dravya Guna Vignana, Vol 2, Choukhambha Bharati Academy, Varanasi; 1998.

Cite this article as:
Usha Patil. Standardization and quality evaluation of selected single drug formulations (choornas) from an Ayurvedic pharmacy. Int. J. Res. Ayurveda Pharm. 2014;5(4):457-460 http://dx.doi.org/10.7897/2277-4343.05494

Source of support: Nil, Conflict of interest: None Declared