Academic Sciences International Journal of Pharmacy and Pharmaceutical Sciences

ISSN- 0975-1491 Vol 4, Issue 4, 2012

Research Article

STANDARDIZATION OF POLYHERBAL FORMULATION "*VYOṢĀDI GUGGULU*" FOR OBESITY

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Received: 20 Jun 2012, Revised and Accepted: 25 July 2012

ABSTRACT

Standardization of herbal formulation is essential in order to assess the quality of drugs for therapeutic value. According to an estimate of World Health Organization (W.H.O) nearly 80% of populations of developing countries rely on traditional medicines. The World Health Organization (WHO) in 1999 has given a detail protocol for the standardization of herbal drugs comprising of a single content, but very little literature is available for the standardization of poly-herbal formulation. *Vyoṣādi Guggulu vati* is official in Ayurvedic formulary of India and is prescribed for the treatment of obesity. It is a polyherbal preparation contained ten ingredients. In this research paper, an attempt has been made to develop standardization methods of *Vyoṣādi Guggulu vati*. In-house preparation has been standardized on the basis of macroscopic, microscopic, physic-chemical parameters. The set parameters were found to be sufficient to evaluate the Vati and can be used as reference standards for the quality control/quality assurance laboratory of a Pharmaceutical house.

Keywords: *Vyoṣādi Guggulu*, Polyherbal, Quality control/quality assurance.

INTRODUCTION

Obesity is a condition of abnormal body weight resulting from an accumulation of extra adipose tissue, generally in response to a state of positive energy balance that occurs when intake exceeds energy expenditure. It is a growing global health problem in the present era. Obesity is a chronic relapsing, stigmatized neurochemical disease that is more prevalent in developing and developed countries and leading to much comorbidities[1].There are great need of standardization and quality control of ayurvedic formulations in order to justify their acceptability in modern system of medicine. Standardization and quality control depends upon the nature of crude drug and compound drugs, it's source i.e. factors associated with raw materials which are beyond of human control like seasonal, geographical, age of the plant, time of collection, type of drying etc. due to these natural conditions, the percentage of chemical constituents [2,3]of the drug does no remain uniform as our expectation. The need of quality control for ayurvedic drug is due to the fact that the preparation of drug according to the ancient method has been reduced due to the commercialization of ayurvedic pharmacy The absence of post-market surveillance and the paucity of test laboratory facilities also make the quality control of ayurvedic medicines exceedingly difficult at this time[4].Therefore, an attempt has been made to standardize *Vyoṣādi Guggulu vati*, an Ayurvedic formulation as prescribed in Ayurvedic Formulary, used in obesity (Table 1).

Table 1: *Vyoṣādi Guggulu* contains following ingredients:

Sanskrit name		Scientific name	Part used	Quantity
1.	Śunthī	*Zingiber officinale* Rosc.	(Rz.)	1 part
2.	Marica	*Piper nigrum* L.	(Fr.)	1 part
3.	Pipalī	*Piper longum* L.	(Fr.)	1 part
4.	Agni (citraka)	*Plumbago zeylanica* L.	(Rt.)	1 part
5.	Mustā	*Cypeprus rotundus* L.	(Rz.)	1 part
6.	Harītakī	*Terminalia chebula* Retz.	(P.)	1 part
7.	Bibhitakā	*Terminalia belerica* Roxb.	(P.)	1 part
8.	Āmalaki	*Emblica officinale* Gaertn.	(P.)	1 part
9.	Vidanga	*Embelica ribes* Burn.f.	(Fr.)	1 part
	Guggulu-śuddha	*Commiphora wightii* (Arn.) Bhandari	(Exd.)	9 parts

MATERIALS AND METHODS

Physico-chemical studies like total ash, water soluble ash, acid insoluble ash, water and alcohol soluble extract, loss on drying at 105°C and successive extractive values by soxhlet extraction method were carried out as per the WHO guide lines[5]. Preliminary phytochemical tests were performed as per the standard methods[6].

Procurements of Drugs

Polyherbal formulation consists of 10 ingredients, viz., *Zingiber officinale, Piper nigrum, Piper longum, Plumbago zeylanica, Cypeprus rotundus, Terminalia chebula, Terminalia belerica, Emblica officinalis, Embelia ribes, Commiphora wightii.* The crude drugs were purchased from the local crude drug market, Kharibaoli and their identity was confirmed by Dr. H. B. Singh, expert taxonomist.

Prepration of *Vyoṣādi Guggulu* Vati

Wash the each ingredients of the formulation, and then allow for drying. After drying, powder the each ingredients of the formulation and pass through sieve number 120. Then weigh them separately in the required quantities and mix. After this, add Eranda oil to an extent required to facilitate the pounding and continue pounding till a semisolid uniformly mixed mass of suitable plasticity is obtained. Expel the mass through Vati machine and cut the Vati to a desired weight. Roll the Vati and dry in a tray-dryer at a temperature not exceeding 60º for 10 to 12 h[4] (Fig 1).

Macroscopic study

It refers to evaluation of the formulation by color, odor, taste, texture, etc. The macroscopic study of the samples was evaluated based on the method described by Siddiqui *et al*[7] (Table 2).

Table 2: Organoleptic properties of polyherbal formulation

Appearance	Color	Odor	Taste	Texture
Spherical pills	Blackish brown	Pleasant	Bitter	Fine

Fig. 1: Prepared *Vyoṣādi Guggulu vati*

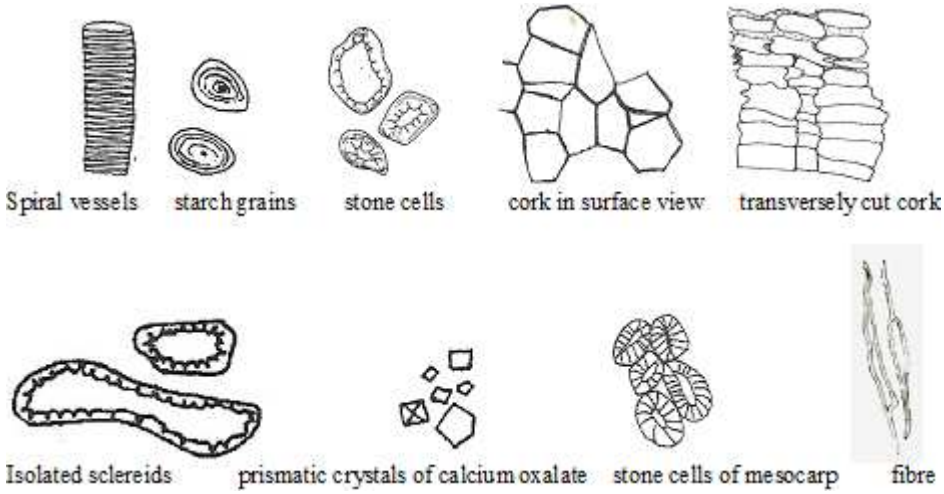

Fig. 2: Microscopical characters of formulation

Microscopic study

For microscopic study, 5 g of the drug sample was taken, powdered. The powdered material was taken on a 85 mesh sieve and allowed in slow running water for washing away the minerals. The materials were cleared in chloral hydrate, wash with distilled water and mounted in glycerin, then observed charcters[8] (Fig 2).

Physico-chemical parameters study

Physico-chemical parameters such as foreign matter, moisture content, total ash and acid insoluble ash, water- and alcohol- soluble extractives test were determined according to methods described in the Indian Pharmacopoeia[8] (Table 3).

Determination of resin content

The accurately weighed drug sample (5gm) was rapidly refluxed with acetone (3 X 200ml) for 6 hours to exhaust the drug for the resin content. The excess solvent was removed by distillation on a water bath. The residue so obtained was suspended in water and transferred to a separating funnel, repeatedly extracted the suspension with solvent ether (2 X 200ml) to extract all the resin contents. The ether extracts were cooled out dried over anhydrous sodium sulphate and excess ether removed over a water bath. It was transferred to a weighed beaker and the final weight is noted [12] (Table 3).

Determination of fat content

A weighed quantity of polyherbal formulation (3gm) was extracted with anhydrous ether in a continuous extraction apparatus for six hours the extract is filtered into a clean dry weighed flask. The extraction flask was rinsed with small quantity of ether, filtered and added to the weighed flask. The solvent was evaporated and dried to constant weight at 105ºC [12] (Table 3).

Foaming index and foreign matter analysis

Foaming index as per WHO guidelines[5] and foreign matter analysis was also done to remove impurities [12] (Table 3).

Phytoconstituents study

The presence of different phytoconstituents viz. alkaloids, glycosides, flavonoids, steroids, triterpenes, saponins, tannins, carbohydrates, proteins and amino acids were determined following standard procedure[8] (Table 4).

Florescence analysis

Many herbs fluorescence when cut surface or powder is exposed to UV light and this can help in their identification method [9, 10] (Table 5).

Powdered drug reaction with different reagents

The powdered drug was treated separately with different reagents and acids like, picric acid, hydrochloric acid, nitric acid, iodine, ferric chloride, and sodium hydroxide the colour shown by that treatment is noted as such and under the microscope [11] (Table 6).

Table 3: Physiochemical characteristics of polyherbal formulation

S. No.	Parameter	Percentage mean (n=3) ± SD
1	Water soluble extractive (w/w %)	36.59± 0.34
2	Alcohol soluble extractive (w/w %)	33.69± 0.49
3	Hexane soluble extractive (w/w %)	13.62± 0.67
4	Chloroform soluble extractive (w/w %)	17.62 ± 0.33
5	PET soluble extractive (w/w %)	12.11 ± 0.24
6	Ash content (w/w %)	07.33 ± 0.11
7	Acid insoluble ash (w/w %)	01.05 ± 0.27
8	Moisture content	6.45 ± 0.8
9	pH (1%)	4.62± 0.3
	(10%)	4.70± 0.2
10	Fat content	5.3 ± 0.1
11	Resin content	7.78± 0.7
12	Foaming index	<1
13	Foreign matter analysis	0.07

Table 4: Phytochemical screening

Extract constituents	Pet. Ether	Acetone	Chloroform	Alcoholic	Hydro-Alc	Aqueous
Alkaloids	-	+	++	+	+	-
Carbohydrates	-	-	-	-	+	+
Glycosides	-	-	-	+	+	+
Phenolics	-	-	-	+	++	++
Flavonoids	-	-	-	+	+	+
Proteins & A.A	-	-	-	-	+	+
Saponins	-	-	-	-	-	+
Mucilage	-	-	-	-	-	-
Resins	+	++	++	++	+	+
Lipids/fats	++	++	++	+	+	-
Sterol	++	++	+	+	+	-

Table 5: Fluorescence analysis

S. No.	Treatment	Day light	UV light 254n m	UV 366 nm
1.	Powder as such	Buff yellow	Buff yellow	Buff yellow
2.	Powder treated with dist. H_2O	Buff yellow	Buff yellow	Light black
3	Powder treated with 5% aq. NaOH	Yellow	Light green	Black
4.	Powder treated with NH_3	Green	Light green	Black
5.	Powder treated with conc. H_2SO_4	Dark brown	Light brown	Black
6.	Powder treated with 50% HCl	Light pink	Light brown	Black
7.	Powder treated with 50% HNO_3	Dark brown	Brown	Black
8.	Powder treated with 5% Iodine	Brown	Light brown	Dark brown
9.	Powder treated with 5% Ferric chloride solution	Greenish black	Dark green	Black
10.	Powder treated with Picric acid	Yellow	Greenish yellow	Black

Table 6: Powdered drug reaction with different reagents

S. No.	Chemical treatment	Observation
1.	Iodine	Dark brown
2.	Glacial acetic acid	Off white
3.	Ferric chloride 5%	Greenish black
4.	Lead acetate	Yellowish green
5.	Potassium hydroxide 1%	Orange yellow
6.	Picric acid	Yellow
7.	1N HCl	Light pinks
8.	1N H_2SO_4	Cherry red
9.	50% HNO_3	Orange

Determination of physical characteristics of powder formulation

Bulk density, tap density, Haussner ratio, and Carr's index were physical characteristics used for different formulations[13, 14, 15, 16].

Bulk density and Tap density

The term bulk density refers to a measure used to describe a packing of particles or granules. The equation for determining bulk density (D), Db=M/Vb Where, M is the mass of the particles and V is the total volume of the packing. 100gm of weighed formulation powder was taken, added to the cylinder. Typically the initial volume was noted and the 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

Angle of Repose has been used as an indirect method of quantifying powder flow ability because of its relationship with interparticle cohesion. The fixed funnel and the free standing cone method

employs a funnel that is secured with its tip at a given height, which was taken 2.5 cm (H), above the graph paper that is place on flat horizontal surface. Powder or granulation was carefully poured through the funnel until the apex of the conical pile just touched the tip of the funnel. Tan _ = H/ R or _ = arc tan H/R Where _ is the angle of repose, R being the radius of the conical pile.

Hausner ratio

It 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: Df / Do, where Df = Tapped density and Do = Bulk density (Table 7).

Table 7: Physical properties of polyherbal formulation

Parameters	Values
Bulk density	0.33 gm/ml
Tap density	0.66 gm/ml
Angle of repose	20.95
Haussners ratio	1.54

RESULTS AND DISCUSSION

Formulation was prepared in accordance with the Ayurvedic Formulay of India. The finished product *Vyoṣādi Guggulu vati* was tested for relevant physical and chemical parameters as per standardization procedure. The organolepti properties of the in-house formulations were reported in table 1. Quality tests for different *Vyoṣādi Guggulu vati* and its individual ingredients were performed for moisture content, ash content, water soluble extractive, methanol soluble extractive, acid insoluble ash and water insoluble ash, and were found to be within standard ranges. The extractive values and ash values of individual ingredients of vati and in-house formulation given in table 2 and 3 respectively. The results are expressed as mean (n=3) ±Standard deviation (SD).Variations were observed in most of the physicochemical parameters studied. The total ash value of formulation was found to be higher than that for its ingredients. The extractive values of formulations in water were found to be much higher than alcohol extractive values. Moisture content at (105ºC) and pH of 1% w/v and 10% w/v aqueous solution are also presented in Table 3. pH of 1% and 10%w/v solution revealed that the formulations are acidic in nature. In fluorescence analysis the powder samples were exposed to ultraviolet light at wavelength of 254nm and 366nm and day light after being treated with different reagents as reported in table 4. Fluorescence analysis results shows whether any fluorescent ingredients are present or not, here we have found there was no such material found in formulation. The physical characteristics of the in house are shown in Table 7. The flow ability of the formulation was found to be poor in formulation, which was further confirmed by high values of Hausner ratio. Foaming index, foreign matter analysis, fat content and resin content was tabulated in table 3.

It showed the characters in the mount like parenchyma cells intercepted with stone cells, perisperm cells (*Piper nigrum*), stone cells (*Piper longum*), parenchyma cells with adherent oleoresincells (*Zingiber officinale*)(Figure 1).

CONCLUSION

Ayurvedic medicine *Vyoṣādi Guggulu* has been standardized by intervention of sctientific quality control measures in the traditional preparation describe in classicial texts. Pharmacognostic characters established for the raw material could be employed as Q.C, The outcomings of research can be used for evaluating the quality and purity of the formulations for the polyherbal phyto formulation.

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