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Research Article

QUALITY CONTROL EVALUATION OF IN-HOUSE PREPARED POLYHERBAL AYURVEDIC FORMULATION SAPTAVIMSATIKA GUGGULU

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ABSTRACT

Objective: The usage and dose of traditional medicines which are in random and unspecified are a big challenge for acceptance as a medicine until not get standardized. The most important ayurvedic drugs, i.e., Saptavimsatika Guggulu have selected from ayurvedic famous books named Ayurvedic Pharmacopoeia of India ayurvedic monographs for phytochemical and physicochemical study. These ayurvedic drugs are mainly and commonly used in the treatment of heart, skin, and stomach-related disease. Drug preparation was done during an event organized by our university under theme Rx-thon. However, no any standardize data are available of this formulation; hence, an objective is made to standardize this formulation for future aspects.

Materials and Methods: Physicochemical and phytochemical study such as extractive value, ash value, moisture content, pH values, true density, bulk density, angle of repose, Carr's index, Hausner's ratio, fluorescence analysis, and thin-layer chromatography was covered in the study.

Results: Phytochemical study revealed that reducing sugars, tannin, phenolic compounds, saponin glycosides, and gum were present in the sample. Various physicochemical parameters had been studied in the standardization procedures and were compared with reference standards. The extractive, ash values, and fluorescence analysis were done and were compared to reference standard.

Conclusion: The physicochemical standardization of polyherbal formulation Saptavimsatika Guggulu was carried out. The individual ingredients of the formulation were authenticated and standardized as per the WHO guidelines and Indian Herbal Pharmacopoeia. The in-house formulation was prepared and studied for various physicochemical properties. Although no marketed sample is available; hence, a probability is made under standard evaluation parameter to launch this product in market for sale.

Keywords: Ayurvedic, Polyherbal phytochemical, Saptavimsatika Guggulu.

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INTRODUCTION

Standardization is the process of implementing and developing technical standards based on identifying inherent characteristics, constant parameters, and definitive qualitative and quantitative values which can produce assurance of quality, efficacy, safety, and reproducibility. It is the process of developing and approving on technical standards [1]. The subject of herbal drug standardization is massively wide and deep [2]. For the research work on quality control parameters of herbal formulations, a deep knowledge about the important herbs found in India and widely used in ayurvedic formulation is very important. India can play the lead role in production of traditional formulation and can become major country for trade of these formulations. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques of standardization [3]. Specific standards are set to carry out the experimentation, which would lead to the development of a set of characteristics exhibited by the particular herbal medicine. Standardization of herbal formulations is important to check the quality of drugs on the basis of active chemical constituent. However, in the formulation, there is multiple chemical constituent, but the active one remains unknown [4]. This makes the procedure of standardization so exigent. To assure the quality of the drug, concentration of active constituents and the therapeutically benefits with purity and efficacy are the major aspects. Saptavimsatika Guggulu is a polyherbal ayurvedic classical formulation used in angina pectoris, cough, asthma, intercostal neuralgia inflammation, piles, fistula-in-ano, pelvic pain, pain in mouth, pain in anus, and calculus [5].

MATERIALS AND METHODS

Plant material

Saptavimsatika Guggulu consists of 28 ingredients, namely *Zingiber officinale*, *Piper nigrum*, *Piper longum*, *Terminalia chebula*, *Terminalia bellirica*, *Emblica officinalis*, *Saussurea lappa*, *Embelia ribes*, *Tinospora cordifolia*, *Plumbago zeylanica*, *Hedychium spicatum, Elettaria cardamomum, Piper longum* (stems), *Juniperus communis, Cedrus deodara*, *Zanthoxylum aromaticum, Saussurea lappa* stems, *Piper chaba, Citrullus colocynthis, Berberis aristata, Trachyspermum ammi*, *P. longum* (stems), salts (*Saindhava lavana, Vida lavana,* and *Sauvarchala lavana*), *Hordeum vulgare, Scindapsus officinalis,* and *Commiphora wightii* [6]. All these ingredients were procured from the local market of Dehradun, Uttarakhand, and India and were authenticated by botanist Dr. R. K. Soni, Survey Officer, Botanical Garden, Indore. A voucher specimen of the same has been deposited in the museum of Botanical Garden for future reference.

Preparation of Saptavimsatika Guggulu

The Guggulu was prepared as per the procedure given in Ayurvedic Formulary of India. All the ingredients of the pharmacopoeia mentioned quality were taken. The ingredients were washed, dried, and powdered separately except Guggulu. These were than pass through sieve numbered 85. All ingredients were separately weighed in the required quantities and were mixed well. The weighed quantity of Guggulu was crushed and fine powder of other mixed ingredients added to it and was pounded well. Small quantity ghrita was added at regular intervals for smooth pounding and continue pounding till a semisolid uniformly mixed mass of suitable plasticity was obtained. Then, the small pieces of the mass were rolled between the palms to form round or oval shape.

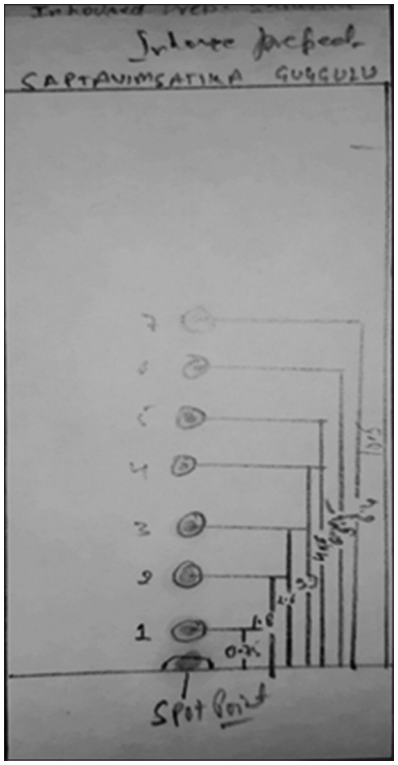

Fig. 1: Thin-layer chromatography of Saptavimsatika Guggulu

These round balls were kept in oven to dry at 40–60°C [7]. To the dried masses, sugar powder was sprinkled, and then, these were packed in tightly closed containers to protect from light and moisture.

Organoleptic evaluation

Organoleptic evaluation refers to evaluation of the formulation by color, odor, taste, texture, etc. The organoleptic characters of the samples were evaluated based on the method described by Siddiqui *et al*.

Pharmacognostical investigations

Pharmacognostical investigations of formulations were carried out, including the determination of extractive values, successive extracts, and ash values. Successive extracts were prepared using Soxhlet apparatus [8].

Determination of pH and moisture content

The pH of different formulations in 1% w/v and 10% w/v of water-soluble portions was determined using pH paper (range 3.5–6 and 6.5–1.4) with standard glass electrode at 240°C [9]. Moisture content was determined by Sartorius moisture balance.

Determination of physical characteristics of powder formulation

Physical characteristics such as bulk density, tap density, angle of repose, Hausner's ratio, and Carr's index were determined for different formulations. 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 (jolting volumeter) that has a specially cut rotating can. 100 g of weighed formulation powder was taken and carefully added to cylinder with the aid of a funnel. The first volume was noted and sample was then tapped until no further reduction in volume was noted. The first reading gave the bulk density value and after tapping the volume reduced, it gives the value of tapped density. Angle of repose has been used as an indirect method quantifying powder flowability due to its relationship with interparticle cohesion. The fixed funnel and the free-standing cone method employ an apparatus that is secured with its tip at a given height (H) above the glass paper that is placed on a flat horizontal surface. Powdered drug was poured through the funnel until the top of the conical pile just touched the tip of funnel. Thus, with R being the radius of the conical pile, tan a=H/R or a=arc tan H/R, where a is the angle of repose. Hausner's ratio is related to interparticle friction and as such can be used to predict the powder flow properties [10]. The equation for measuring the Hausner's ratio is D_f/D_0, where D_f is the tapped density and D_0 is the 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

$$I= (D_f-D_0/D_f) \times 100$$

Where, D_f is the tapped density and D_0 is the bulk density.

Fluorescence analysis

The powdered samples were exposed to ultraviolet (UV) light at wavelengths of 254 and 366 nm. Fluorescence analysis was carried out in accordance with the procedure reported by Kokoshi *et al*. Few quantity of powdered drug was placed on a Petri dish and observed under UV 366 and UV 254 and in daylight to observe the fluorescent characteristics of powder, if any [11]. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml 1 N HCl and observed under UV 366 and UV 254 and in daylight while wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml 1 N NaOH and observed after a few

Table 1: Physiochemical evaluation of Saptavimsatika Guggulu

S. No.	Material/analysis	Result
Organoleptic characters		
1	Appearance	Round solid pill
2	Color	Brown
3	Odor	Characteristic
4	Taste	Bitter
Extractive values (% w/w)		
1	Alcohol soluble	18.954±1.268
2	Water soluble	16.677±1.340
Successive extracts (% w/w)		
1	Petroleum ether	2.33
2	Chloroform	1.34
3	Ethyl acetate	4.56
4	Benzene	4.76
5	Ethanol	12.54
6	Methanol	10.23
7	Aqueous	11.78
Ash values (% w/w)		
1	Total ash	0.834±0.082
2	Acid-insoluble ash	0.596±0.067
3	Water-soluble ash	0.234±0.046
4	Sulfated ash	0.003±1.260
pH values		
1	1% w/v	7.02±0.126
2	10% w/v	6.06±0.055
Moisture content		
1	% moisture	8.11±0.947

Table 2: Physical studies on Saptavimsatika Guggulu

S. No.	Parameters	Results
1	Bulk density	0.3692 g/cm^3
2	Tapped density	0.5641 g/cm^3
3	Angle of repose	46.17
4	Carr's index	34.55
5	Hausner's ratio	1.528

Table 3: Fluorescence analysis of Saptavimsatika Guggulu

S. No.	Drug + Reagent	Short UV 254 nm	Long UV 366 nm	Visible
1	Powder	Bluish-brown	Bluish-brown	Brown
2	Powder + 1 N HCl	Dark green	Dark green	Green
3	Powder + 1 N NaOH	Dark brown	Brown	Brown
4	Powder + 1 N NaOH in Methanol	Brown	Brown	Brown
5	Powder + 50% KOH	Bluish-black	Bluish-black	Dark blue
6	Powder + 50% H_2SO_4	Dark brown	Dark brown	Dark brown
7	Powder + Conc. H_2SO_4	Brown	Dark brown	Dark brown
8	Powder + 50% HNO_3	Reddish-brown	Reddish-brown	Brownish-black
9	Powder + Conc. HNO_3	Reddish-brown	Reddish-brown	Brownish-black
10	Powder + Acetic acid	Brown	Brown	Brown
11	Powder + Iodine solution	Dark violet	Dark violet	Violet

UV: Ultraviolet

Table 4: Phytochemical study of various extracts of Saptavimsatika Guggulu

S. No.	Phytochemicals	Pet. ether extract	Chloroform extract	Ethyl acetate extract	Ethanol	Water
1	Carbohydrate	–	–	–	–	+
2	Alkaloids	+	+	–	+	–
3	Glycoside	–	+	–	+	+
4	Tannin	–	–	+	+	+
5	Flavonoids	–	–	+	–	+
6	Saponins	–	–	+	+	+
7	Terpenoids	–	–	+	+	+
8	Gums and mucilages	–	+	–	+	+
9	Phenolics	–	+	+	+	+

–: Absent, +: Present

Table 5: TLC data of Saptavimsatika Guggulu

Name of drug	Number of spots observed	Distance travel by solvent (cm)	Distance travel by solute (cm) InH	Rf value InH
Saptavimsatika Guggulu	7	10.5	0.75	0.07
			1.8	0.17
			2.6	0.25
			3.7	0.35
			4.6	0.44
			5.5	0.52
			6.4	0.61

TLC: Thin-layer chromatography

minutes in daylight, under UV 366 and UV 254. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml 1 N NaOH in 1 ml methanol and observed under UV 366 and UV 254 and in daylight while still wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml 50% KOH and observed under UV 366 and UV 254 and in daylight while still wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml of 50% sulfuric acid and observed under UV 366 and UV 254 and in daylight while still wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml of concentrated sulfuric acid and observed under UV 366 and UV 254 and in daylight while still wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml of 50% HNO_3 and observed under UV 366 and UV 254 and in daylight while still wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml of concentrated HNO_3 and observed under UV 366 and UV 254 and in daylight while still wet. 1 mg powdered drug was placed on a microslide and treated with 1 ml of acetic acid and observed under UV 366 and UV 254 and in daylight while still wet. Few quantity powdered drug was placed on a Petri dish and treated with 1 ml of iodine and observed under UV 366 and UV 254 and in daylight while still wet.

Phytochemical investigation

The aqueous and ethanol extract of formulation were prepared and were investigated for the presence of chemical constituent, namely alkaloid, glycoside, tannin, flavonoids, saponins, carbohydrate, terpenoids, gums, and mucilage. [11,12].

Thin-layer chromatography (TLC)

TLC is particularly important for the determination of quality. TLC is a technique in which a solute undergoes distribution between a stationary phase acting through adsorption and a mobile phase in the form of liquid. The adsorbent is a thin uniform layer of dry finely powdered material silica gel, applied to a glass plate, are the most communally used [13]. Separation achieved on the basis of partition or adsorption depending on the particular types of support its preparation and its use with different solvent system.

Stationary phase: Silica gel 60 F_{254}

Mobile phase: Toluene:ethyl acetate:formic acid (5:15:0.5)

RESULTS AND DISCUSSION

In-house formulation was prepared as per formula in Ayurvedic Formulary of India. Water-soluble and alcohol-soluble extractive values and ash values (total ash and acid-insoluble ash) were determined. The ash values of the samples were estimated based on the method as described by the WHO guidelines for medicinal plant materials. The physicochemical and organoleptic comparisons between in-house formulations and marketed formulations were studied. Acid-insoluble ash value for in-house formulation was found to be 0.596±0.067 (average value along with standard deviation); in case of marketed formulation, this was found to be 0.573±0.108. The pH of 1% w/v and 10% w/v solutions revealed that pH values of both the formulations were comparable and were slightly acidic

for both the formulations. The phytochemical investigation of various extracts shoes marked the presence of maximum chemical constituent, but ethyl acetate extract, ethanol extract, and water extract show significant presence of chemical constituent. The comparative readings were done using ANOVA and Student's t-test. TLC profile helps to give a proper analysis of chemical present in extract of drug as compare all the Rf values with reference standards.

CONCLUSION

The physicochemical standardization of polyherbal formulation Saptavimsatika Guggulu was carried out. The individual ingredients of the formulation were authenticated and standardized as per the WHO guidelines and Indian Herbal Pharmacopoeia. The formulation was prepared in laboratory and studied for evaluating various physicochemical properties. Although no marketed sample is available; hence, a probability is made under standard evaluation parameter to launch this product in market for sale.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest for collecting and compiling and also for paper publication.

AUTHORS' CONTRIBUTIONS

The authors in this research have equally contributed in collecting and compiling the data.

REFERENCES

1. Organisation Mondiale De La Sante. Quality Control Methods for Medicinal Plant Materials. Vol. 559. Geneva: World Health Organisation; 1992. p. 159-165.
2. Ekka NR, Nmedo KP, Samal PK. Standardization strategies for herbal drugs. Res J Pharm Tech 2008;1:310-2.
3. Anonymous. World Health Organisation: Quality Control Methods for Medicinal Plant Materials. Delhi: AITBS Publishers; 2002. p. 65-7.
4. Mosihuzzamann M. Protocols on safety, efficacy, standardization and documentation of herbal medicines. IUPAC Pure Appl Chem 2008; 80:2195-230.
5. Anonymous, Quality Control Methods for Medicinal Plant Materials. Geneva, New Delhi: AITBS Publishers; 2002. p. 65-7.
6. The Ayurvedic Formulary of India. Government of India, Ministry of Health and family welfare. Vol. 2. New Delhi: Department of ISM and H; 2003. p. 245-8.
7. Hakim MA. Format for the Pharmacopoeial Analytical Standards of Compound Formulation, Workshop on Standardization of Unani Drugs, (Appendix). Vol. 4. New Delhi: Central Council for Research in Unani Medicine (CCRUM); 1995. p. 456-8.
8. Anonymous, Indian Pharmacopoeia, Ministry of Health and Family Welfare. Vol. 1. New Delhi: GOI; 2010. p. 10-146.
9. Lachman L, Liberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy. Vol. 2. Bombay: Varghese Publishing House; 1987. p. 145-6.
10. Chitra RK, Shah B. Phytochemical screening and standardization of polyherbal formulation: Maharishi amrit kalash. Int J Pharm Pharm Sci 2014;6:96-8.
11. Satheesh NV, Kumud U, Asha B. Phytochemical screening and standardization of poly herbal formulation for dyslipidemia. Int J Pharm Pharm Sci 2011;3 Suppl 3:235-8.
12. Khandelwal KR. Practical Pharmacognosy, Techniques and Experiments. Vol. 12. Pune: Nirali Prakashan; 1996. p. 58-9.
13. Harbone JB. Phytochemical Method a Guide to Modern Technique of Plant Analysis. Vol. 2. New York: Champman and Hall; 1984. p. 113-7.