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Formulating and assessing polyherbal Syrup

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Abstract:
Background and objectives: People's interest in traditional medicine has increased recently; however, traditional herbal medicines should be transformed into modern forms of medicine to increase patient acceptance. In this investigation, a polyherbal traditional combination has been done and its quality control evaluations have been performed.
Methods: The formulation's primary components including Kalmegh, Adhatoda Vasaka, Turmeric, Cinnamon were crushed, mixed and extracted using the decoction technique and distilled water. The mixture accustomed to prepare formulations of the syrup Total phenolics content of the formulation was established after studying the syrup's physicochemical, microbiological, and rheological characteristics.
Results: The syrup was a light brown colour and was semitransparent. It had an acceptable taste and smell. There was precipitation but no cap locking.. Dry residue, sedimentation, pH, viscosity, density and total phenolics were found to be 14.82%, 0.015%, 5.40, 4.6 cP, 1.076 g/mL and 127.34 mg/100 mL, respectively. Syrup's microbiological analysis complied with the WHO protocol.
Conclusion: This study's output, a pharmaceutical standardised formulation, supports the notion of drug development based on conventional wisdom
Keywords: Kalmegh, Adhatoda Vasaka, Turmeric, Cinnamon

INTRODUCTION

Traditional medical systems are potential resources to discover new medicines. The popularity of traditional, complementary, and alternative medicine has grown throughout the world [1]. Many academics in Iran and throughout the world have been interested in Indian traditional medicine (ITM) because of its illustrious history and effective therapies. Existing therapies mentioned in ancient Indian scriptures have

been the subject of several studies and clinical trials [2]. ITM is a well-known health care system among several conventional medical systems because of its foundational idea of humours. It holds that a healthy body is created by the four humors—phlegm, black bile, yellow bile, and blood—being in balance, whereas disease is caused by an imbalance. [3]. "Balgham" (phlegm) (with cold and wet qualities) is one of these humors and the imbalance of this humor causes many disorders such as stroke [4,5], hemiplegia due to ischemic stroke [6], cardiovascular disease risk factors such as metabolic abnormalities like abdominal obesity, high cholesterol, high blood pressure and high blood glucose[7],overweight [8],atherosclerosis [9], vitiligo [10,11], impotency[12-14], polycystic ovary syndrome (PCOS) [15] and premature ovarian failure (POF) [16] in human body according to modern research. Treatment would include the evacuation of morbid or excess humors from the body [17, 18]. "Herbal syrup" formulations are known to be useful to evacuate morbid matters produced due to excess or putrefaction of phlegm and is widely used for diseases with cold and moist temperament (diseases occurring due to phlegm accumulation) [17].

Different formulations of "Herbal syrup" were found in ITM textbooks, among diverse prescriptions, a combination of Kalmegh AdhatodaVasaka Turmeric Cinnamon been put to use in this study in the form of decoction according to "Herbal Syrup", an ITM reference book, prescription [19]. Since "Herbal syrup" is still served as a traditional cure, it is needful to prepare a suitable formula for facilitating its use for patients [2]. For ease of administration and greater patient acceptance compared to the old formulations that must be produced for each usage, traditional medications should be converted into novel pharmacological forms. Also, to ensure a suitable and reproducible treatment response, a regular dose form must be used. [3, 20]. Syrup was made for this study in line with ITM regulations, and a quality control analysis was done on it.

MATERIAL AND METHODS

Plant materials

All required plants for formulation of the syrup were purchased from local market. samples from the herbal market of the roots of Kalmegh, Adhatoda Vasaka, Turmeric, Cinnamon cotton thistle, Glycerin, pyrogallol, and folin-Ciocalteu were bought from the German-based Merck Co. 1 Sigma-Aldrich supplied the sodium benzoate, potassium sorbate, and sodium bicarbonate.

Evaluation of the plants' quality control

The plants' quality control tests were conducted in accordance with the monograph pharmacopoeias [21-23]. Preparation of the multi-herbal syrup. Consequently, the selected traditional resource [19], Kalmegh, AdhatodaVasaka, Turmeric, Cinnamon, coarsely powdered and extracted using the decoction technique and distilled water (plant: water 1:10 w/v) for 30 min. The mixture was filtered. Finally, sodium benzoate and potassium sorbate (0.3 and 0.2%, respectively) were increased to the mixture as microbial preservatives. Carbomer 940 (0.5-1%), in order to produce the proper viscosity for formulation), The effects of propylene glycol (PG) (8,12,16, and 20%), glycerin (8,12,16, and 20%), carboxymethyl cellulose (CMC) (0.5-1%), hydroxypropyl methyl cellulose (HPMC) (0.5-1%), poly vinyl pyrrolidone (PVP) (5%), and glycerin (8,12,16, and 20%) were studied.

Glycerin-containing formulations may be used, so F8–F11 formulations were created and their physicochemical characteristics were assessed. F10 was identified as the optimum formulation based on the findings.

Physical-chemical testing of the polyherbal syrup's quality

The prepared syrup was subjected to a number of physiochemical tests and pharmaceutical parameters, such as macroscopic characteristics, crystallisation evaluation, cap locking, sedimentation, dried residue, pH, density, viscosity measurement, evaluation of rheological properties, short-term thermal stability, and microbial evaluations. [24].

Phenolic content overall

Using the British Pharmacopeia's Folin-Ciocalteu reagent, the product's total phenolics content was quantified. [21]. In a nutshell, distilled water was used to dilute 1 mL of the syrup to 10 mL. One mL of 2 mL of the diluted syrup was combined with 10 mL of distilled water, followed by the addition of the Folin-Ciocalteu reagent. After being diluted with sodium carbonate (29% w/v) to a volume of 25 mL, the solution was left to sit at room temperature for 30 minutes. At 760 nm, the absorbance was measured. Pyrogallol's calibration curve was used as the standard to determine the amount of total phenolics in the sample. At room temperature, triplicates of each measurement were made.

Physicochemical characteristic of F8 to F11 formulations: -

Tests	Formulation			
	F8	**F9**	**F10**	**F11**
Color	**Pale brown**	**Pale brown**	**Pale brown**	**Pale brown**
Test	**Bitter**	**Bitter sweet**	**Sweet**	**Very sweet**
Appearance	**Mostly translucent**	**Greater clarity than F8**	**Greater clarity than F9**	**Greater clarity than F10**
Viscosity	**3.9 ± 0.33**	**4.3 ± 0.42**	**4.6± 0.30**	**5.1± 0.26**
Density	**1.048± 0.002**	**1.064± 0.001**	**1.076± 0.001**	**1.092± 0.001**
pH	**5.17± 0.03**	**5.29± 0.05**	**5.40± 0.03**	**5.49± 0.04**

Thermal stability over a short time

Three bottles of syrup were kept in a freezer (4° C), and three additional samples were kept in an incubator (40° C). The samples were changed seven days later. The samples were frequently examined for changes like sedimentation, taste, odour, and colour after the fourteen-day cycle.

The relative viscosity and clarity of the syrup were both increased by glycerin and PG, however different amounts of PG were unpalatable (F12-F15). Glycerin produced a clear, viscous liquid with sweet flavours that increased viscosity, increased the syrup's transparency, and also covered over the taste. (F8- F11).

The syrups were made using various amounts of glycerin in order to find the ideal formulation. The attributes of different concentrations of the syrup with a glycerin base utilised in the experimental formulations are shown in the table.Increased glycerin ratio was found to improve the characteristics of experimental formulations. improved the syrup's viscosity and altered its flavour and appearance (F10-F11). As high levels of glycerin (F11) generated an unfavourable, too sweet flavour, formulation F10 was selected as the best formulation for making polyherbal syrup. Glycerin was thus added to the syrup as a sweetener, viscosity-increasing agent, co-solvent, stabiliser, and transparency-enhancing agent. To create a product that was as close to the original as feasible, flavouring and colouring ingredients were omitted while sodium benzoate and potassium sorbate were employed as antimicrobial preservatives.

Syrup quality control's study revealed that it had the optimum visual properties without any indications of cap locking and crystallization. Neither centrifugation nor short-term thermal stability testing revealed any evidence of physical alterations. The polyherbal syrup's rheological behaviour was also identified.

Final version of the multi-herbal syrup

Ingredients	Amount (%)	Function
Kalmegh	32	Active constituent
Adhatoda Vasaka	16	Active constituent
Turmeric	16	Active constituent
Cinnamon	16	Active constituent
Glycerin	16(ml)	Co-solvent, Viscosity-increasing agent,
Sodium benzoate	0.3	Preservative
Potassium sorbate	0.2	Preservative
Water	q.s. to100	Solvent

RESULT AND DISCUSSION: -

Analysing physicochemical data and the outcomes of polyherbal syrup's expedited stability testing

Specification	Start	After 1 month
Appearance	Pale brown more translucent liquid	Conforming
Taste	Appropriate	Conforming
Odor	Characteristic	Conforming
pH	5.40±0.03	5.33±0.05
Dried residue (%)	14.82±0.73	14.88±0.32
Sedimentation (%)	0.015±0.000	0.015±0.000
Density (g/mL)	1.076±0.001	1.076±0.001
Viscosity (cP)	4.6±0.3	4.8±0.2
Total phenolics content (mg/100 mL)	127.34±0.42	125.66±1.03
Conclusions on stability		Stable

The accelerated stability test results have been displayed. in table after one month. The total amount of phenolics was measured as the marker using Folin-Ciocalteu reagent. Pyrogallol, at a concentration of 6.37 mg/5 mL, was discovered in the syrup.. After one month, According to the maximum permitted reduction (5%) the decline in the phenolics contents has been decreased to 1.31% and 2.50%, which is appropriate. [25]. Within a month, the microbiological test results were in line with WHO recommendations. Based on the outcomes of the accelerated stability test, no statistically significant changes ($p>0.05$) regarding the measured parameters throughout a month were discovered, confirming the product's stability. The polyherbal syrup, according to physical properties and microbiological quality control tests, demonstrated adequate stability after a month at 40 °C and was satisfactory as an oral product.

In this research, “Herbal syrup” Syrup was reformulated with the proper physicochemical properties, and quality assurance procedures were created. A new conventional formulation of "Herbal" can be used in clinical trials with this formulation.

CONCLUSION: -

The polyherbal syrup was formulated using the standard method. The last version (F10) was created and is more stable than previous formulations. F8, F9, F11. The expression (F10) was obtained by minimizing the error in formulation F1, F2, F3. The formulation (F10) was tested for various rheological parameters and stability studies were also carried out for the syrup.

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