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Research Article

STANDARDIZATION AND EVALUATION OF TWO MARKETED POLYHERBAL FORMULATION (GUTIKAS)

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ABSTRACT

Objective: The study was designed as standardization and evaluation of two marketed polyherbal formulation (gutikas) for the treatment of skin disorder and antibacterial.

Methods: Selected marketed polyherbal formulations were containing tulsi *(Ocimum sanctum)* and neem (*Azadirachta indica*) as a main ingredient. The standardization of the two polyherbal formulation was carried out as per official guidelines, in which the polyherbal tablet formulation was subjected that physiochemical characterization, phytochemical, and pharmaceutical parameter would serve as the identity of this polyherbal formulation.

Results: Phytochemical test indicates the presence of alkaloid, glycosides, terpenoids, tannins, and steroids in both formulations. Parameters for loss of drying, pH, ash values, and extractive values documented. Pharmaceutical parameters, such as hardness, friability, weight variation, and disintegration, were found to be within acceptable values.

Conclusion: From the result, it was concluded that polyherbal formulation of tulsi and neem tablet passes all the standardization and evaluation parameters and developed quality standard which can be used as a quality standard for polyherbal formulation.

Keywords: Ayurvedic formulation, Marketed Gutikas, Standardization.

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INTRODUCTION

The word Ayurveda (Sanskrit word) is the form in the combination of "Ayur" means life and "Veda" means knowledge or science which means "the science of life," and based on the theory of Tridosha. According to the WHO report, approximately 70% of population using ancient medicinal system in India and the demand for this system is gradually amplified day by day [1]. Pharmaceutical formulation containing a natural product like herbs as an active constituent is known as herbal medicinal system. The efficiency of the active constituent is based on the right time and atmospheric condition for the collection and processing [2].

According to a recent current issue in many journals, most of the researchers have an enormous curiosity in a herbal medicinal system for a healthy life because it contains most of the natural element with no side effect for preventing the cause of the disease [3]. For maintaining and assessing the polyherbal drug, safety, and efficacy, standardization is an important factor.

In present research, work is to standardization and evaluation of two Patanjali marketed polyherbal formulation (tulsi and neem gutikas). Tulsi (*Ocimum sanctum*) gutika (tablet) is used as antibacterial, spasmolytic, and immune-modulatory agent and neem *(Azadirachta indica)* gutika (tablet) have a spermicidal and antimicrobial activity, hence used in skin disorder. According to the WHO guidelines for standardization and evaluation of herbal formulation chemical, biological, quantitative, and qualitative, measures are required. Hence, to prove the composition and quality of polyherbal marketed formulation, adequate analytical methods are used for evaluation.

METHODS

Collection of sample

The sample of tulsi ghanvati 40 g and nimb ghanvati 40 g was purchased from the registered Divya pharmacy store (Uttarakhand).

Phytochemical analysis

The presence of alkaloid, carbohydrates, glycosides, proteins, steroids, tannins, and terpenoids in gutikas was evaluated by the standard test [4].

Physiochemical evaluation

Ash value (Table 1).

Determination of extractive value

Determination of alcohol-soluble extractive value: In a conical flask, 5 g of the drug was macerated with 100 ml alcohol for 1 day, shaking after every 6 h and filtered. Evaporated 25 ml of filtrate in Petri dish at 105°C and weighed the solid matter.

Determination of water-soluble extractive value: In a conical flask, 5 g of the drug was macerated with 100 ml water for 1 day, shaking after every 6 h and filtered. Evaporated 25 ml of filtrate in Petri dish at 105°C and weighed the solid matter.

Loss on drying

Taken 1–2 g of the powdered drug in Petri dish and spread it evenly. Kept the dish in the oven at a temperature between 100 and 105°C for 2 h. Cooled the sample in desiccator, weighed the sample, and calculated % of loss on drying.

pH

In a beaker, 5 g of the sample was dissolved with water and covered it with aluminum foil. Allow to withstand in room temperature for 24 h. After 24 h, decanted the supernatant liquid and determined the pH using pH meter [5-9].

Pharmaceutical analysis

Hardness

The hardness of gutikas was evaluated using hardness tester.

Table 1: Procedure of total ash, acid-soluble ash, and water-soluble ash

Method	Total Ash	Acid-soluble ash	Water-soluble ash
Step I	Incinerate 2–3 g of powdered drug in tared silica crucible at a temp not above 45°C	Boiled the ash with 25 ml of conc. hydrochloric acid for 5 min	In 25 ml water, total ash was boiled for 5 min
Step II	Allow to cool in desiccator and weighted (X)	Filtered it and the solid matter was collected on an ashless filter media	Insoluble matter was filtered and collected on ashless filter media
Step III	Calculate the percentage of ash.	Solid matter was washed with hot water and ignited in crucible	Insoluble matter washed with hot water and ignited in crucible
Step IV	_____	Allowed to cool in desiccator and weighed	Allowed to cool in desiccator and weighed
Step V	_____	Calculate the percentage of acid-insoluble ash	Calculate the percentage of water-soluble ash
Step VI	_____	Acid-insoluble ash = Total ash – solid matter	Water-soluble ash = Total ash – insoluble solid

Friability

Dedust the ten tablets weighed and kept in a curved part of the plastic chamber and closed the lid. Switched on and rotate it with 25 rpm for 100 times. After completion of the cycle, open the lid, remove dust from tablets, and reweighed it. Values are compared with the IP standard.

Disintegration test

On USP device, taken six tablets on each tube covered and poured it on 1000 ml beaker. After 28–32 cycle per min at temp 37°C in 1.2 pH buffer, disintegration time was noted and compared the value with the standard.

Weight variation

Weighed 20 tablets and calculated its average weight. Values are compared with the standard [10-12].

RESULTS

Phytochemical analysis

The presence of phytochemical constituents mentioned in Table 2.

Physiochemical parameters

The mean percentage of physiochemical parameters, that is, ash value, extractive value, loss of drying, and pH value of tulsi and neem tablets is shown in Table 3. Marketed formulations are also free from any heavy metals.

Pharmaceutical analysis

In pharmaceutical analysis, hardness (kg/cm), friability (%), weight variation, dissolution, and disintegration time (min) were determined, all the value under the IP limits and depicted in Table 4.

Table 2: Phytochemical analysis of tulsi and neem tablet

Phytochemical constituents	Tulsi	Neem
Alkaloids	++	++
Glycosides	++	++
Tannins	++	––
Saponin	––	––
Carbohydrates	––	++
Steroids	++	++
Terpenoids	++	++
Proteins	––	––

++ indicates presence, –– indicates absence

Table 3: Physiochemical parameters of tulsi and neem tablet

Parameters	Tulsi tablet	Neem tablet
Acid-insoluble ash value (%)	5.6%±0.043	1.33±0.040
Water-soluble ash value (%)	10.8±0.0219	3.6±0.210
Total ash (%)	8.8±0.041	5.33±0.033
Alcohol-soluble extractive value (%)	21.6±0.012	62.4±0.058
Water-soluble extractive value (%)	42.6±0.031	53.6±0.052
Loss of drying (g)	0.16±0.02	0.26±0.003
pH value	6.5±0.002	7.8±0.001

Table 4: Pharmaceutical analysis of tulsi and neem tablet

Parameters	Tulsi tablet	Neem tablet
Hardness (kg/cm^2)	7±0.046	7.5±0.003
Friability (%)	0.48±0.010	0.16±0.015
Weight variation	±5%	±5%
Disintegration time (min)	36 min	38 min

DISCUSSION

Selected polyherbal tablets are commonly formulation for a skin disorder and antibacterial diseases, but its standardization has not performed yet; hence, the present work has been done.

In phytochemical analysis, it shows the presence of alkaloids, glycosides, tannins, steroids, and terpenoids and due to the presence of terpenoids in tulsi and neem tablets shows the spasmodic and antibacterial activity, respectively. Ash value is a tool to determine drug authenticity and purity. The total ash and water-soluble ash value was found to be high in both polyherbal formulations which indicate that presence of high mineral content and less acid-insoluble ash value indicates presence of less earthy content like nitrogen, argon, helium, carbon.

Extractive value is indicated the nature of chemical constituents and helps to the identification of adulterants. Tulsi tablets show high water extractive value, that is, maximum drug content present in water, and the neem tablet shows high alcohol extractive value indicate alcoholic nature of drug.

Loss on drying was found to be 0.16±0.02 g and 0.26±0.003 g for tulsi and neem tablet, respectively. Loss of drying indicates the presence amount of water and volatile substances in a formulation. More moisture level in formulation becomes an ideal medium for the growth of different types of bacteria and fungi affecting the purity, quality, and efficacy of a drug.

The pH of tulsi and neem tablet was found to be 6.5±0.002 and 7.8±0.001, which is slightly acidic and alkaline in nature, respectively.

Hardness and friability of tulsi and neem tablet were found to be 7±0.046 and 7.5±0.003 and 0.48±0.010 and 0.16±0.015, respectively. Both are in acceptable limits and indicate tablet strength during processing and transportation. The average weight of both polyherbal tablets was found to be in IP limits (i.e., ±5%).

The disintegration time of tulsi and neem polyherbal tablets was recorded in the acidic buffer at 37°C is 36 and 38 min, respectively.

CONCLUSION

As a part of standardization procedure, both samples (tulsi and neem) were tested for relevant physiochemical parameters. Result for physicochemical parameters such as the water-soluble, acid-soluble extractive values, total

ash value, water-soluble ash, acid-insoluble ash moisture content, pH, and loss on drying and pharmaceutical characteristics such as hardness, friability, weight variation, and disintegration test was calculated and found to be within the acceptable values.

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AUTHORS' CONTRIBUTIONS

Sonia Paliwal performed all the experimental work and conceptualized all the research outcomes and wrote and edited the manuscript.

CONFLICTS OF INTEREST

There are no conflicts of interest in the publication of the paper.

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